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EXHIBIT 2

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June 20, 2006

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FILING DATE: *July 08, 1999*
PATENT NUMBER: *6,582,408*
ISSUE DATE: *June 24, 2003*

By Authority of the
Under Secretary of Commerce for Intellectual Property
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W. MONTGOMERY
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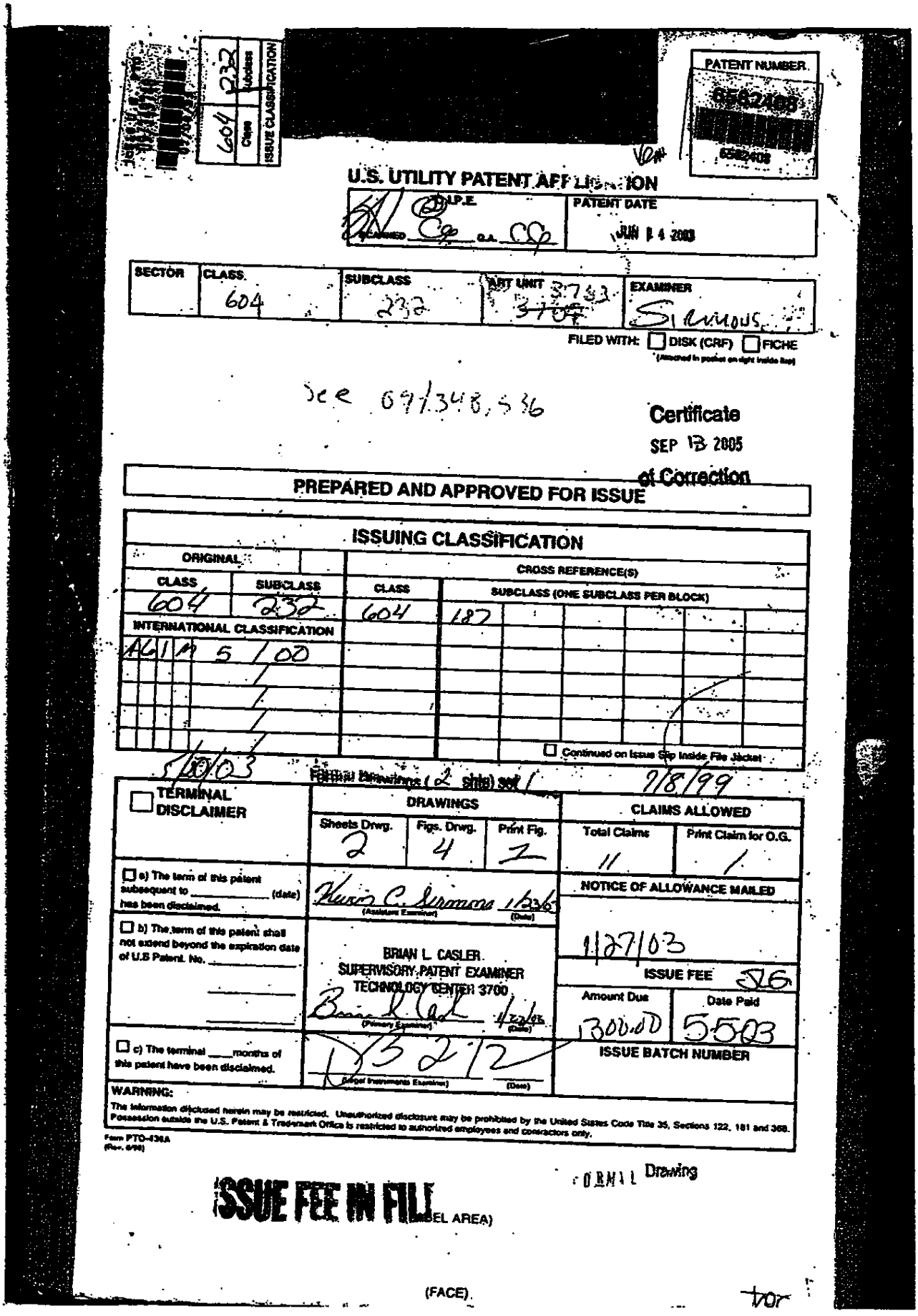

ISSUE CLASSIFICATION: Class 604, Subclass 232

PATENT NUMBER: 6582403

U.S. UTILITY PATENT APPLICATION

EXAMINED E.P.E. Eg Q.A. CSP

PATENT DATE: JUN 24 2003

SECTOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
	604	232	3743 3704	Simmons

FILED WITH: ☐ DISK (CRF) ☐ FICHE

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See 09/348,536

Certificate SEP 13 2005 of Correction

PREPARED AND APPROVED FOR ISSUE

ISSUING CLASSIFICATION

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604	232	604	187

INTERNATIONAL CLASSIFICATION: A61M 5/00

☐ Continued on Issue Slip Inside File Jacket

5/20/03 Formal Drawings (2 ship) rec'd 9/8/99

☐ TERMINAL DISCLAIMER	DRAWINGS Sheets Drwg.	Figs. Drwg.	Print Fig.	CLAIMS ALLOWED Total Claims	Print Claim for O.G.
	2	4	1	11	1

☐ a) The term of this patent subsequent to _____ (date) has been disclaimed.

Kurt C. Simmons 1/26 (Assistant Examiner) (Date)

NOTICE OF ALLOWANCE MAILED 9/27/03

☐ b) The term of this patent shall not extend beyond the expiration date of U.S Patent. No. _____

BRIAN L. CASLER SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700

Brian L Casler 4/22/03 (Primary Examiner) (Date)

ISSUE FEE $86

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☐ c) The terminal ___ months of this patent have been disclaimed.

DS 2/12 (Legal Instruments Examiner) (Date)

ISSUE BATCH NUMBER

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Form PTO-436A (Rev. 6/98)

FORMAL Drawing

ISSUE FEE IN FILE (LABEL AREA)

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(12) **United States Patent**
Buch-Rasmussen et al.

(10) **Patent No.: US 6,582,408 B1**
(45) **Date of Patent: Jun. 24, 2003**

(54) **MEDICAL DEVICE**

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(22) Filed: **Jul. 8, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/098,707, filed on Sep. 1, 1998.

(30) **Foreign Application Priority Data**

Jul. 8, 1998 (DK) ..... PA 1998 00910
Nov. 17, 1998 (DK) ..... PA 1998 01501

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(52) U.S. Cl. 604/232; 604/187
(58) Field of Search 604/186, 187, 604/232, 188, 192, 195, 207–218, 200, 201, 228, 233, 234

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,744,790 A		5/1988	Jankowski et al.	604/232
4,865,591 A	*	9/1989	Sams	604/186
4,973,318 A		11/1990	Holm et al.	604/208
4,990,142 A		2/1991	Hoffman et al.	604/232
5,364,369 A	*	11/1994	Reynolds	604/187
5,688,251 A		11/1997	Chanoch	604/208

FOREIGN PATENT DOCUMENTS

EP	0 702 970 A2	3/1996	
WO	WO 93/00948	1/1993	
WO	WO 94/21213	9/1994	
WO	WO 95/13842	5/1995	
WO	0 688 571 A1	12/1995	
WO	WO 96/02290	2/1996	
WO	WO 97/49620	12/1997	
WO	WO 99/16487	4/1999	

OTHER PUBLICATIONS

Abstract of Australian patent application AU–A–73 632/81.

* cited by examiner

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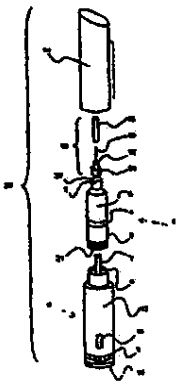
(57) **ABSTRACT**

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger. Furthermore, the cartridge assembly has one end sealed with a pierce able sealing, said end comprising coupling device for engaging a needle assembly, and another end comprising coupling device for engaging the dosing assembly. The dosing assembly comprises a plunger and has coupling device for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The device further comprises mechanism for securing that the plunger abuts on the stopper during use of the device, in particular when the dosing assembly is releasable coupled to the cartridge assembly. The securing mechanism is preferably a mechanism for preventing the cartridge assembly from being inadvertently released from the dosing assembly. The cartridge is preferably molded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The medication delivery device is especially suitable for delivering insulin, growth hormone or the like medicines.

11 Claims, 2 Drawing Sheets



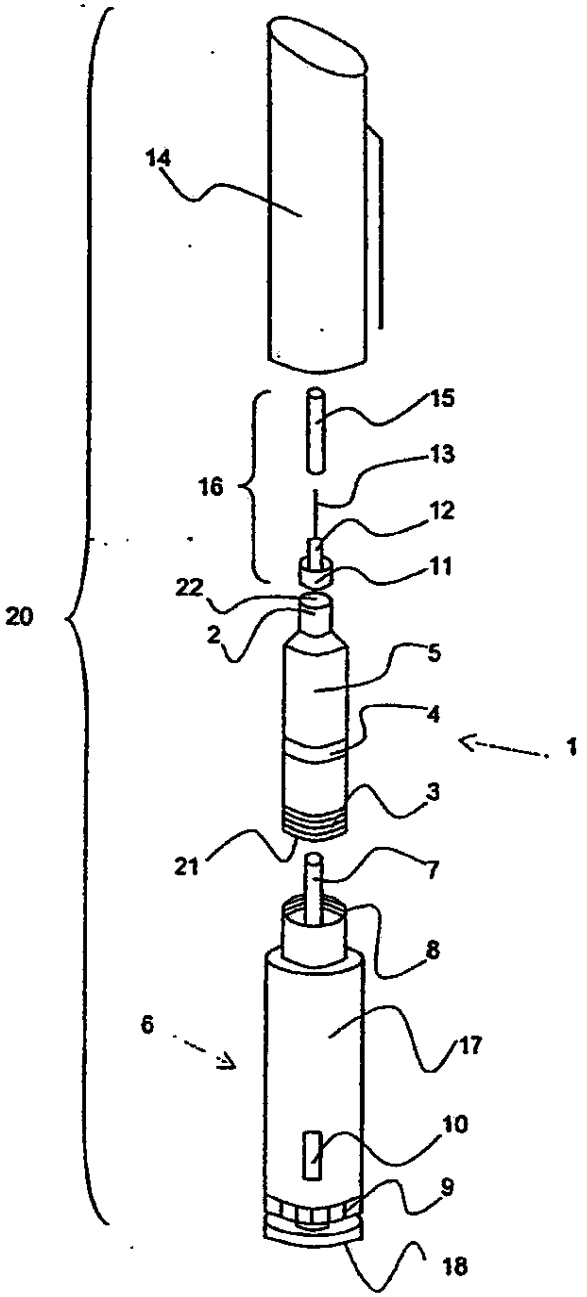


Fig. 1

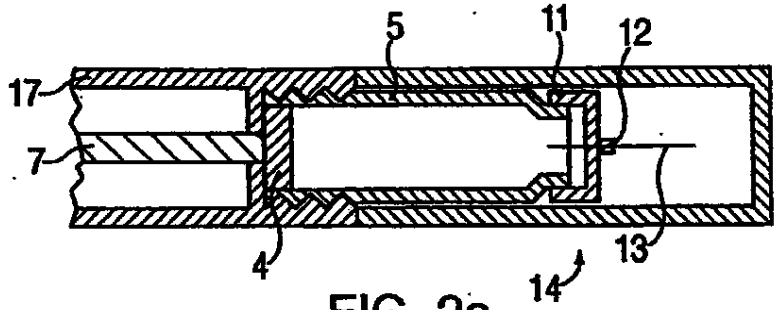


FIG. 2a

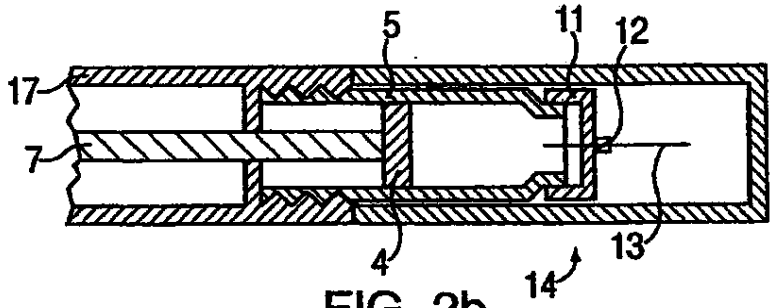


FIG. 2b

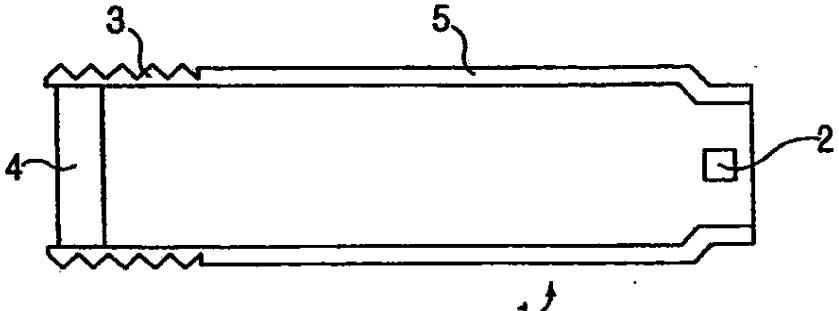


FIG. 3

MEDICAL DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of Danish application serial nos. PA 1998 00910 filed Jul. 8, 1998, PA 1998 01501 filed Nov. 17, 1998, and U.S. Provisional application serial No. 60/098,707 filed Sep. 1, 1998, the contents of which are fully incorporated herein by reference.

BACKGROUND

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly, thereby delivering the medication. When the medication in the cartridge is exhausted, the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be replaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the cartridge only.

An example of prior art pens is disclosed in EP 0 688 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasable receive a needle cannula assembly through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly, whereby the pen is ready for dosing the medicine within the cartridge. The cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced.

However, a drawback of the above-mentioned pen is that the driving means of the pen body may be disengaged from the plunger of the cartridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 688 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle assembly from the cartridge assembly the cartridge assembly may inadvertently be released or partly released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the cartridge. In particular if the pen body assembly is only partly released from the cartridge assembly the user will most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine.

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to fasten and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandgrain, for example) to the smoothest going coupling will necessitate a greater force to fasten/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

SUMMARY OF THE INVENTION

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a pierce able sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasable coupled to the cartridge assembly.

By the term "use of the device" is meant the normal use, including metering and delivering the medication, removing a cap from the cartridge assembly and/or needle as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly

together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the stopper in the cartridge when the user attaches the needle assembly or removes it after use. Thereby the user can be confident of the accuracy of the dosage selected.

The means for coupling the dosing assembly and the cartridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasable coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another prefered embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

According to the invention preferred combinations of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap coupling, a bajonet lock or a luer lock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention. The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end sealed with a pierce able sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily molded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily molded with the cartridge. In the latter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

In another embodiment the invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

DRAWINGS

FIG. 1 is an exploded perspective view of the medication delivery device.

FIG. 2 is a cross-sectional view showing part of the medication delivery device, 2*a* immediately after assembling before the first injection, and 2*b* after some time of use.

FIG. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

DETAILED DESCRIPTION OF THE INVENTION

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in FIG. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in FIGS. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means and, accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment, the dosing assembly 6 includes a cylindrical housing 17 surrounding the plunger means of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in FIGS. 1 and 2, and in greater detail in FIG. 3. In FIG. 1 cartridge assembly 1 includes a molded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasable mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one or both of the couplings 2, 3 of the cartridge may be molded unitarily with the housing.

In a preferred embodiment at least one of the couplings 2, 3 is molded unitarily with the cartridge 5, minimising the

total number of parts of the device and thereby the production costs. Also, a very precise coupling is obtained, since no further steps are to be taken to attach the coupling means to the cartridge.

Instead of the protective housing the cartridge 5 may have integrally molded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

In FIG. 1 and FIG. 2 the couplings 2, 3 are opposing each other having the same axis. However, the axis of coupling 2 may be arranged to be separate from coupling 3; that is in any angle with respect to the axis of coupling 3. Thus, the axis of coupling 2 may be perpendicular to the axis of coupling 3, or they may be parallel but not overlapping.

A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether any content, such as a liquid is left in the cartridge.

Referring to FIG. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are molded unitarily with the cartridge.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the needle at the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

What is claimed is:

1. A medication delivery device comprising:

a cartridge assembly comprising a cartridge having a pierceable seal at one end and a moveable stopper at an opposite end;

a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;

a needle assembly;

a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the second coupling means is selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

2. The medication delivery device of claim 1, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.

3. The medication delivery device of claim 2, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein the snap lock is an integral part of the needle assembly.

4. A medication delivery device upon which a needle assembly can be mounted, the device comprising:

a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;

a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set doseage;

a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and

a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper; and

wherein the first or second coupling means comprises a snap lock.

5. The medication delivery device recited in claim 4, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.

6. The medication delivery device of claim 4, wherein the first coupling means comprises a means for uncoupling

through an axial movement of the cartridge assembly relative to the dosing assembly.

7. The medication delivery device of claim 4, wherein the first coupling means comprises a threaded coupling means.

8. The medication delivery device of claim 4, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.

9. The medication delivery device of claim 4, wherein the second coupling means comprises a threaded coupling means.

10. A medication delivery device comprising:

a cartridge assembly comprising:

a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and

a needle mounting means for mounting a needle on the cartridge assembly;

a dosage assembly for delivering a set dose of medication, comprising:

a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the plunger means to deliver the set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper;

a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly;

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly; and

wherein at least the first or the second coupling means comprises a snap lock.

11. A medication delivery device comprising:

a cartridge assembly for housing a removable cartridge containing a medication;

a needle assembly;

a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;

a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the second coupling means is chosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling means prevents axial movement of the cartridge assembly relative to the dosage assembly.

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UNITED STATES PATENT AND TRADEMARK OFFICE

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** CONTINUING DATA **********

This appln claims benefit of 60/098,707 09/01/1998

** FOREIGN APPLICATIONS **********

DENMARK PA 1998 00910 07/08/1998
DENMARK PA 1998 01501 11/17/1998

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Foreign Priority claimed	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119 (a-d) conditions met	DENMARK	2	18	2
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[x] yes [ ] no
[ ] yes [x] no [ ] Met after Allowance
Examiner's Signature Initials

#21 ADDRESS 26427 MARC A. BEGEN, ESQ
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100 College Road West
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TITLE

MEDICAL DEVICE

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PTO-1556
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*U.S. GPO: 1998-433-214/60404

Attorney Docket No.: 5533.200-US PATENT

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Applicants: Buch-Rasmussen et al.

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Date of Deposit July 8, 1999

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3. Unexecuted Combined Declaration and Power of Attorney
4. Two Sheets of Drawings

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

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5533.200-US

Your ref: 5533 – Our ref: P 227 P1 (Medical device)

The present invention relates to a medication delivery device having a cartridge assembly and a dosing assembly coupled together for delivering selected doses of medication.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the cartridge only.

An example of prior art pens is disclosed in EP 0 688 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly, whereby the pen is ready for dosing the medicine within the cartridge. The cartridge

holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced.

However, a drawback of the above-mentioned pen is that the driving means of the pen body may be disengaged from the plunger of the cartridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 688 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle assembly from the cartridge assembly the cartridge assembly may inadvertently be released or partly released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the cartridge. In particular if the pen body assembly is only partly released from the cartridge assembly the user will most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine.

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to fasten and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandskorn, for example) to the smoothest going coupling will necessitate a greater force to fasten/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

Summary of the invention

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle

assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

By the term "use of the device" is meant the normal use, including metering and delivering the medication, removing a cap from the cartridge assembly and/or needle as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the stopper in the cartridge when the user attaches the needle assembly or removes it after use. Thereby the user can be confident of the accuracy of the dosage selected.

The means for coupling the dosing assembly and the cartridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

According to the invention preferred combinations of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap

coupling, a bajonet lock or a luer lock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention. The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge. In the latter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

In another embodiment the invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one or both of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

In a preferred embodiment at least one of the couplings 2, 3 is moulded unitarily with the cartridge 5, minimising the total number of parts of the device and thereby the production costs. Also, a very precise coupling is obtained, since no further steps are to be taken to attach the coupling means to the catridge.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

In Fig. 1 and Fig. 2 the couplings 2, 3 are opposing each other having the same axis. However, the axis of coupling 2 may be arranged to be separate from coupling

3, that is in any angle with respect to the axis of coupling 3. Thus, the axis of coupling 2 may be perpendicular to the axis of coupling 3, or they may be parallel but not overlapping.

A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether any content, such as a liquid is left in the cartridge.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

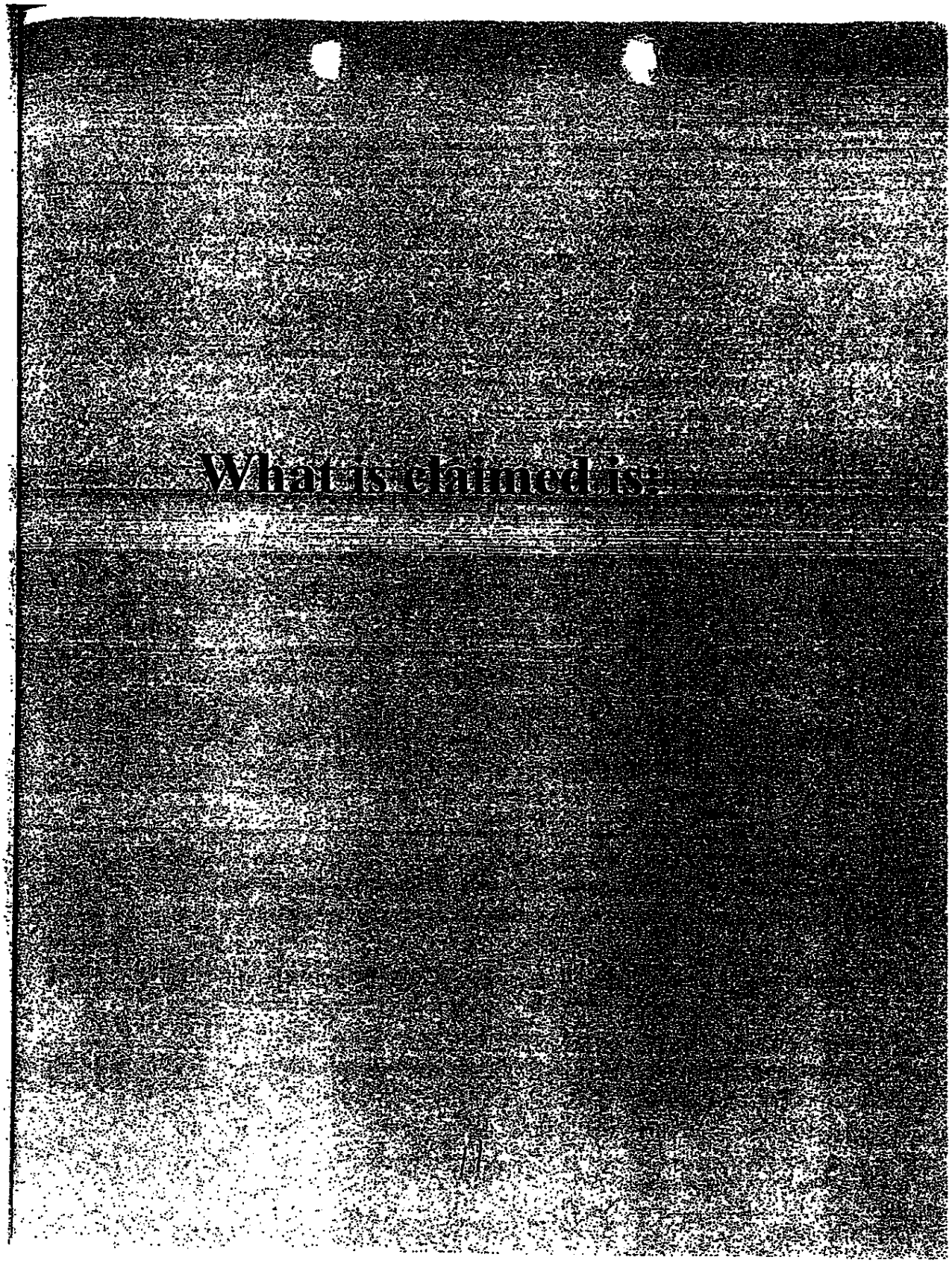
The medication delivery device 20 may further comprise any appropriate needle assembly 11; such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the needle at the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.


What is claimed is:

Claims:

1. A medication delivery device comprising

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

2. A medication delivery device according to claim 1, wherein the dosing assembly is releasably coupled to the cartridge assembly.

3. A medication delivery device according to claim 2, wherein the device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

4. A medication delivery device according to claim 3, wherein the plunger means comprises a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

5. A medication delivery device according to claim 4, wherein the means for releasably coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

6. A medication delivery device according to claim 2, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

7. A medication delivery device according to claim 6, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

8. A medication delivery device according to claim 1, wherein the dosing assembly comprises scale means.

9. A medication delivery device according to claim 1, wherein the dosing assembly comprises dose setting means for defining specified selected doses of medication to be delivered.

10. A medication delivery device according to claim 1, wherein the cartridge assembly comprises a housing.

11. A medication delivery device according to claim 1, wherein the cartridge is unitarily moulded with at least one coupling means.

12. A medication delivery device according to claim 1, further comprising a cap for protecting the needle assembly and/or the cartridge assembly.

13. A cartridge assembly for use in a medication delivery device said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly, further comprising a cartridge said cartridge comprising a slidable stopper.

14. A cartridge assembly according to claim 13, further comprising a housing.

15. A cartridge assembly according to claim 13, wherein the cartridge is unitarily moulded with at least one coupling means.

16. A cartridge assembly according to claim 13, wherein the coupling means adapted to engage the dosing unit is such that coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

17. A cartridge assembly according to claim 13, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

18. A cartridge assembly according to claim 17, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

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Abstract

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger ~~means~~. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling ~~means~~ device for engaging a needle assembly, and another end comprising coupling ~~means~~ device for engaging the dosing assembly. The dosing assembly comprises a plunger ~~means~~ and has coupling ~~means~~ device for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The device further comprises ~~means~~ mechanism for securing that the plunger ~~means~~ abuts on the stopper during use of the device, in particular when the dosing assembly is releasably coupled to the cartridge assembly. The securing ~~means~~ mechanism is preferably a ~~means~~ mechanism for preventing the cartridge assembly from being inadvertently released from the dosing assembly. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The medication delivery device is especially suitable for delivering insulin, growth hormone or the like medicines.

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Atty's Docket Number: 200-US

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Medical Device

the specification of which (check only one item below):

[ ] is attached hereto

[X] was filed as United States application.

Application No. to be assigned

on July 8, 1999,

and was amended

on _____

[ ] was filed as PCT international application

Number _____

on _____,

and was amended under PCT Article 19

on _____

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code, §119 of any provisional or foreign applications(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign applications(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR U.S. PROVISONAL/FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Denmark	PA 1998 00910	July 8, 1998	[X] YES [ ] NO
Denmark	PA 1998 01501	November 17, 1998	[X] YES [ ] NO
USA	60/098,707	September 1, 1998	[X] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

PTO 1391 (REV. 10-83)

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Atty's Docket Number: ,.200-US

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/these prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned

PCT APPLICATIONS DESIGNATING THE U.S.					
APPLICATION NO.	FILING DATE	US SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)				Attorney's Docket Number: 200-US
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6	Full Name of Inventor	Family Name: Jensen	First Given Name: Jens	Second Given Name: Møller
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7	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
8	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
9	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardise the validity of the application or any patent issuing thereon.

Signature of Inventor 3	Signature of Inventor 4	Signature of Inventor 5
Date	Date	Date
Signature of Inventor 6	Signature of Inventor 7	Signature of Inventor 8
Date	Date	Date
Signature of Inventor 9	Signature of Inventor 10	Signature of Inventor 11
Date	Date	Date

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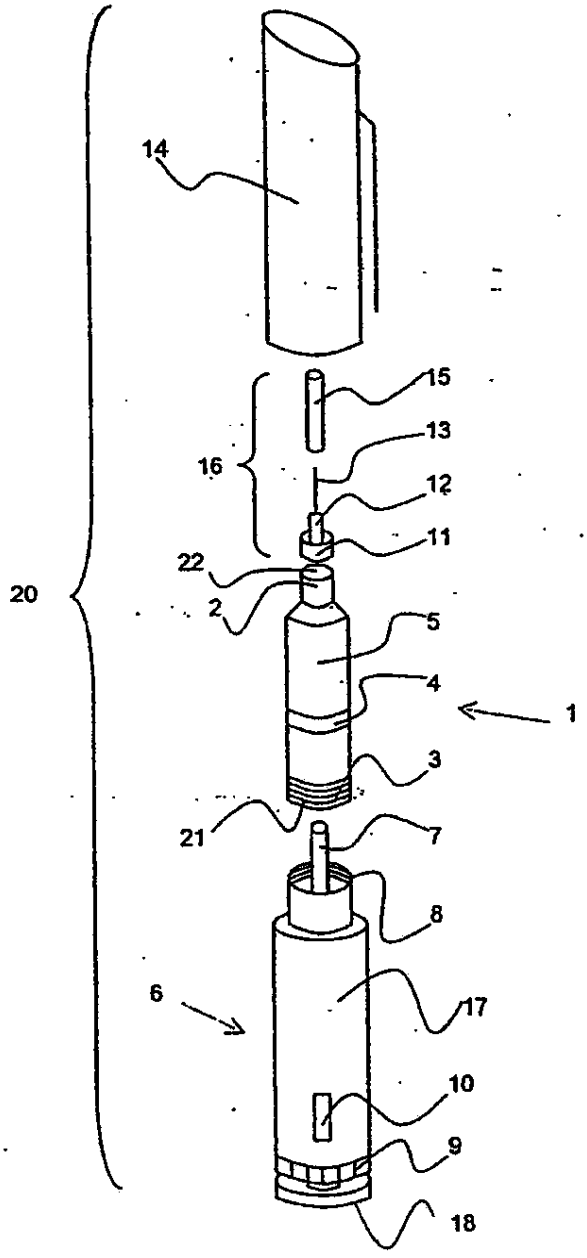

Fig. 1

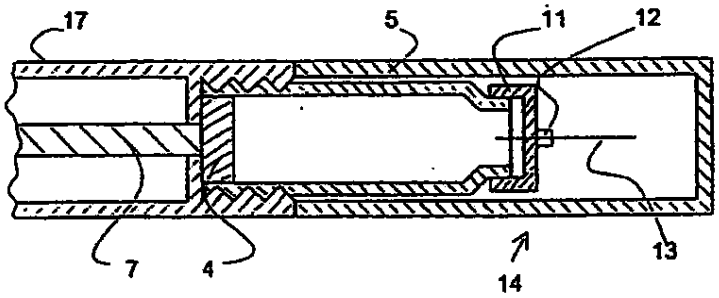

Fig. 2 a

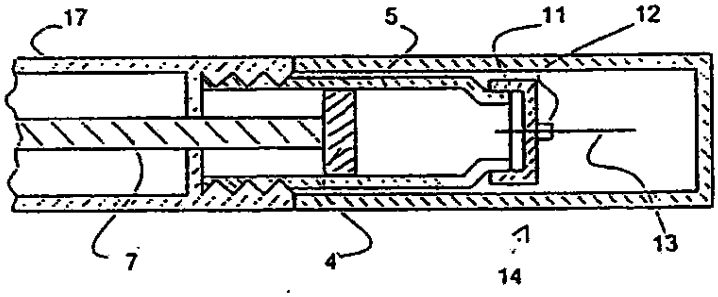

Fig. 2 b

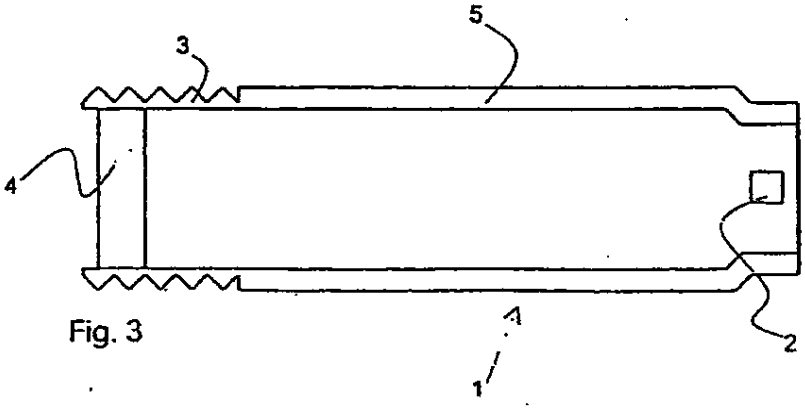

Fig. 3

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/349,743	07/08/99	D	5533.200-05

0262/0805

NOT ASSIGNED

STEVE T ZELSON ESQ
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NEW YORK NY 10174-6400

3734

DATE MAILED: 08/05/99

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☐ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☐ non-small entity is $ 130.

☐ 1. The statutory basic filing fee is:
- ☐ missing.
- ☐ insufficient.

Applicant must submit $ _____ to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☐ 2. Additional claim fees of $_____, including any multiple dependent claim fees, are required.
- $_____ for _____ independent claims over 3.
- $_____ for _____ dependent claims over 20.
- $_____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☐ 3. The oath or declaration:
- ☐ is missing or unexecuted.
- ☐ does not cover the newly submitted items.
- ☐ does not identify the application to which it applies.
- ☐ does not include the city and state or foreign country of applicant's residence.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).
☐ 7. Your filing receipt was mailed in error because your check was returned without payment.
☐ 8. The application does not comply with the Sequence Rules.
See attached "Notice to Comply with Sequence Rules 37 CFR 1.821-1.825."
☐ 9. OTHER: _____

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

_____
Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY

FORM PTO-1533 (REV.9-97)

SECTOR/#13

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748 Group Art Unit: To Be Assigned

Filed: July 8, 1999 Examiner: To Be Assigned

For: Medical Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Response to Notice to File Missing Parts (in duplicate)
2. Copy of Notice to File Missing Parts
3. Executed Combined Declaration and Power of Attorney

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner of Patents and Trademarks
Washington, DC 20231

on October 4, 1999.

Gina Maldonado
(name of person mailing paper)

G Maldonado
(signature of person mailing paper)

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748 Group Art Unit: To Be Assigned

Filed: July 8, 1999 Examiner: To Be Assigned

For: Medical Device

RESPONSE TO NOTICE TO FILE MISSING PARTS

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Missing Parts dated August 5, 1999 (a copy thereof is attached hereto), Applicants submit the Combined Declaration and Power of Attorney signed and dated by Applicants for the above-captioned application.

Please charge the required fee, estimated to be $130.00, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. Please credit any overpayment to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: October 4, 1999

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET/PATENT NO.
09/343,748	02/08/99		5503.200US

0262/0805

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6400

NOT ASSIGNED

3734

DATE MAILED: 08/05/99

NOTICE TO FILE MISSING PARTS OF APPLICATION

Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☐ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☐ non-small entity is $ 130.

☐ 1. The statutory basic filing fee is:
- ☐ missing.
- ☐ insufficient.

Applicant must submit $ _____ to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27)

☐ 2. Additional claim fees of $ _____, including any multiple dependent claim fees, are required.
- $ _____ for _____ independent claims over 3.
- $ _____ for _____ dependent claims over 20.
- $ _____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☒ 3. The oath or declaration:
- ☒ is missing or unexecuted.
- ☐ does not cover the newly submitted items.
- ☐ does not identify the application to which it applies.
- ☐ does not include the city and state or foreign country of applicant's residence.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.

A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application does not comply with the Sequence Rules.

See attached "Notice to Comply with Sequence Rules 37 CFR 1.821-1.825."

☐ 9. OTHER

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

FORM PTO-1533 (REV.9-97)

10/12/1999 MMARSH1 00000130 09343748
01 FC:105 130.00 CH

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)

Attorney's Docket Number: 5200-US

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Medical Device

the specification of which (check only one item below):

[ ] is attached hereto

[X] was filed as United States application

Application No. 09/349,748

on July 8, 1999

and was amended

on

[ ] was filed as PCT international application

Number

on

and was amended under PCT Article 19

on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code, §119 of any provisional or foreign applications(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign applications(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR U.S. PROVISONAL/FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (If PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Denmark	PA 1998 00910	July 8, 1998	[X] YES [ ] NO
Denmark	PA 1998 01501	November 17, 1998	[X] YES [ ] NO
USA	60/098,707	September 1, 1998	[X] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	Docket Number: 200-US

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned

PCT APPLICATIONS DESIGNATING THE U.S.					
APPLICATION NO.	FILING DATE	US SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Steve T. Zelson	Elias J. Lambiris	Valete A. Gregg	Carol E. Rozek	Robert L. Starnes	Reza Green
Reg. No. 30,335	Reg. No. 33,728	Reg. No. 35,127	Reg. No. 36,993	Reg. No. 41,324	Reg. No. 38,475

Send Correspondence to:	Steve T. Zelson, Esq. Novo Nordisk of North America, Inc. 405 Lexington Avenue, Suite 6400 New York, New York 10174-6400		Direct Telephone Calls To: Steve T. Zelson (212) 867-0123
1 Full Name of Inventor	Family Name: Buch-Rasmussen	First Given Name: Thomas	Second Given Name:
Residence & Citizenship	City: DK-2820 Gentofte	State or Foreign Country: Denmark	Country of Citizenship: Denmark
Post Office Address	Post Office Address: Dalvej 28	City: DK-2820 Gentofte	State & Zip Code/Country: Denmark
2 Full Name of Inventor	Family Name: Munk	First Given Name: Benny	Second Given Name:
Residence & Citizenship	City: DK-2650 Hvidorre	State or Foreign Country: Denmark	Country of Citizenship: Denmark
Post Office Address	Post Office Address: Bjæverskov Allé 52	City: DK-2650 Hvidorre	State & Zip Code/Country: Denmark
3 Full Name of Inventor	Family Name: Poulsen	First Given Name: Jens	Second Given Name: Ulrik
Residence & Citizenship	City: DK-2830 Virum	State or Foreign Country: Denmark	Country of Citizenship: Denmark
Post Office Address	Post Office Address: Virumgade 54 C	City: DK-2830 Virum	State & Zip Code/Country: Denmark
4 Full Name of Inventor	Family Name: Ljungreen	First Given Name: Henrik	Second Given Name:
Residence & Citizenship	City: DK-2750 Ballerup	State or Foreign Country: Denmark	Country of Citizenship: Denmark
Post Office Address	Post Office Address: Jonstrupvej 244A	City: DK-2750 Ballerup	State & Zip Code/Country: Denmark

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)				Attorney's Docket Number: 5 .200-US
5	Full Name of Inventor	Family Name: Jensen	First Given Name: Peter	Second Given Name: Møller
	Residence & Citizenship	City: D-2970 Hørsholm	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Svenstrupvej 6	City: D-2970 Hørsholm	State & Zip Code/Country: Denmark
6	Full Name of Inventor	Family Name: Jensen	First Given Name: Jens	Second Given Name: Møller
	Residence & Citizenship	City: DK-1051 Copenhagen K	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Nyhavn 37	City: DK-1051 Copenhagen K	State & Zip Code/Country: Denmark
7	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
8	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
9	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 5	Signature of Inventor 6	Signature of Inventor 7
Date 2/8-99	Date 16/8-99	Date 5-8-99
Signature of Inventor 8	Signature of Inventor 9	Date 2/8 99
Date 18/8-99	Date 23/8-99	Date
Signature of Inventor 3	Signature of Inventor 4	Signature of Inventor 5
Date	Date	Date

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FILING UNDER 37 C.F.R. 1.53(b)

Box Patent Application
Assistant Commissioner for Patents
Washington, DC 20231

Express Mail Label No. EL293688713US
Date of Deposit July 8, 1999

Sir:

This is a request for filing an application under 37 C.F.R. 1.53(b) of

Applicant(s): Buch-Rasmussen et al.

Title: Medical Device

13 pages of specification 2 sheets of formal drawings

3 sheets of Declaration and Power of Attorney

[x] The filing fee is calculated as follows:

Basic Fee:	$ 760.00
Total Claims: 18 - 20 = 0 x 18 =	$ 0.00
Independent Claims: 2 - 3 = 0 x 78 =	$ 0.00
Total Fee:	$ 760.00

Priority of Danish application nos. PA 1998 00910 filed on July 8, 1998 and PA 1998 01501 filed on November 17, 1998 are claimed under 35 U.S.C. 119. Certified copies will follow.

Priority of U.S. provisional application no. 60/098,707 filed on September 1, 1998 are claimed under 35 U.S.C. 119.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of Danish application serial nos. PA 1998 00910 filed July 8, 1998, PA 1998 01501 filed November 17, 1998, and U.S. Provisonal application serial no. 60/098,707 filed September 1, 1998, the contents of which are fully incorporated herein by reference.

12

Address all future communications to Steve T. Zelson, Esq., Novo Nordisk of North America, Inc., 405 Lexington Avenue, Suite 6400, New York, NY 10174-6401.

Please charge the required fee, estimated to be $760, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: July 8, 1999

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

09/112,720

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/349,748	07/08/99	BUCH-RASMUSSEN	T 5533.200-US

QM32/0215

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10174-6400

EXAMINER	
SIRMONS,K	
ART UNIT	PAPER NUMBER
3763	5

DATE MAILED: 02/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95) 1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/349,748	Buch-Rasmussen et al
Examiner	**Group Art Unit**
Kevin C. Simmons	3763

☒ Responsive to communication(s) filed on *Jul 8, 1999*

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-18* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-18* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-12 are, drawn to a medication delivery device, classified in class 604, subclass 232.

   II. Claims 13-18, drawn to cartridge assembly, classified in class 604, subclass 232.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a valve and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Elias J. Lambiris on 2/2/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Simons whose telephone number is (703) 306-5410.

KCS

Kevin C. Simons

Patent Examiner

February 2, 2000

WYNN WOOD COGGINS
SUPERVISORY PATENT EXAMINER

GAU 3734:

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748

Filed: July 8, 1999

For: Medical Device

Group Art Unit: 3734

Examiner: To Be Assigned

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Information Disclosure Statement
2. PTO-1449 Form
3. Copy of References

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner of Patents and Trademarks
Washington, DC 20231

on November 12, 1999.

Carol McFarlane
(name of person mailing paper)

(signature of person mailing paper)

Attorney Docket No.: 5533.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748 Group Art Unit: 3734

Filed: July 8, 1999 Examiner: To Be Assigned

For: Medical Device

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

1. WO 99/16487;
2. Abstract of Australian patent application AU-A-73 632/81;
3. EP 0 702 970 A2;
4. U.S. Patent 4,744,790;
5. U.S. Patent 4,990,142;
6. WO 93/00948;

7. EP 0 688 571 A1;
8. WO 95/13842;
9. WO 94/21213;
10. WO 97/49620;
11. WO 96/02290; and
12. U.S. Patent 4,973,318

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

Respectfully submitted,

Date: November 12, 1999

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Sheet 1 of 1

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 5533.200-US	Serial No. 09/349,748
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant Buch-Rasmussen et al.	
	Filing Date July 8, 1999	Group 3734

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
KCS		4,744,790	05/17/88	Jankowski et al.	604	232	08/19/86
		4,990,142	02/05/91	Hoffmann et al.	604	232	10/23/89
		4,973,318	11/27/90	Holm et al.	604	208	02/09/89

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
		WO 99/16487	04/08/99	WIPO				
		EP 0 702 970 A2	03/27/96	EP				
		WO 93/00948	01/21/93	WIPO				
		EP 0 688 571 A1	12/27/95	WIPO				
		WO 94/21213	09/29/94	WIPO				
		WO 96/02290	02/01/96	WIPO				
		WO 97/49620	12/31/97	WIPO				
		WO 95/13842	05/26/95	WIPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

KCS		Abstract of Australian patent application AU-A-73 632/81

EXAMINER Kevin C. Sirmons DATE CONSIDERED 11/16/08

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

United States Patent [19]

Jankowski et al.

[11] Patent Number: 4,744,790

[45] Date of Patent: May 17, 1988

[54] FAST ACTION CARTRIDGE SYRINGE HOLDER

[75] Inventors: George Jankowski, Media; Michael G. Maletta, Cogan Station; William E. Waters, Malvern, all of Pa.

[73] Assignee: The West Company, Phoenixville, Pa.

[21] Appl. No.: 898,048

[22] Filed: Aug. 19, 1986

[51] Int. Cl.[4] A61M 5/245

[52] U.S. Cl. 604/232; 604/241

[58] Field of Search 604/232, 240, 241, 234, 604/228, 229

[56] References Cited

U.S. PATENT DOCUMENTS

2,423,762	7/1947	Everett	604/241
3,084,688	4/1963	McConaughey	604/232
3,294,089	12/1966	Brookfield	604/241
3,372,697	3/1968	Keller	604/241
4,585,445	4/1986	Haditke	604/234
4,642,103	2/1987	Gettig	604/234

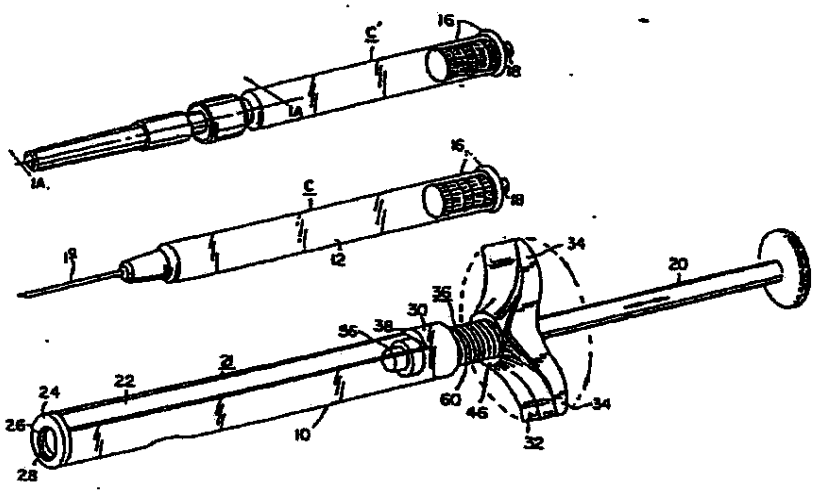
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Eugene E. Renz, Jr.

[57] ABSTRACT

A holder for cartridges or containers for medicaments in injectable form comprising an elongated housing having a pocket for the cartridge, a head assembly including an elongated plunger rod adapted to be attached to the cartridge plunger for actuating the same to effect discharge of medicament from the cartridge and means operatively connecting the head assembly to one end of the housing for actuating a shank portion of the head assembly axially (longitudinally) in the housing. The head assembly and housing is made of dissimilar materials to facilitate relative rotation of the head assembly and housing and resist slippage when the shank exerts an axial force on the cartridge to seat it in the housing.

14 Claims 7 Drawing Sheets



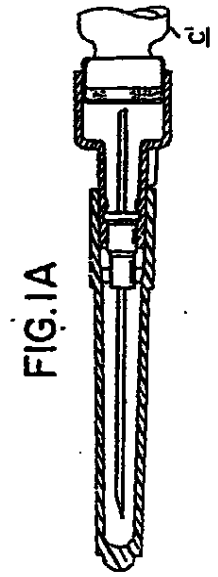


FIG.1A

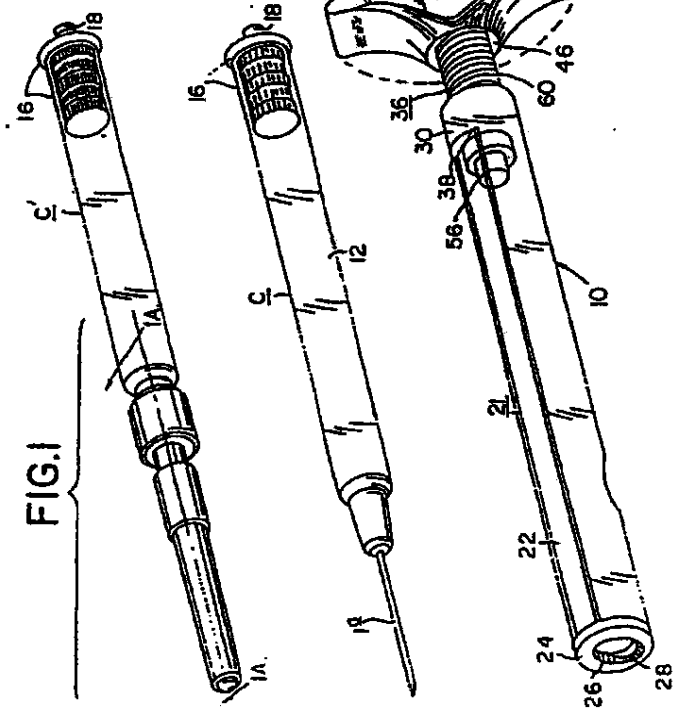


FIG.1

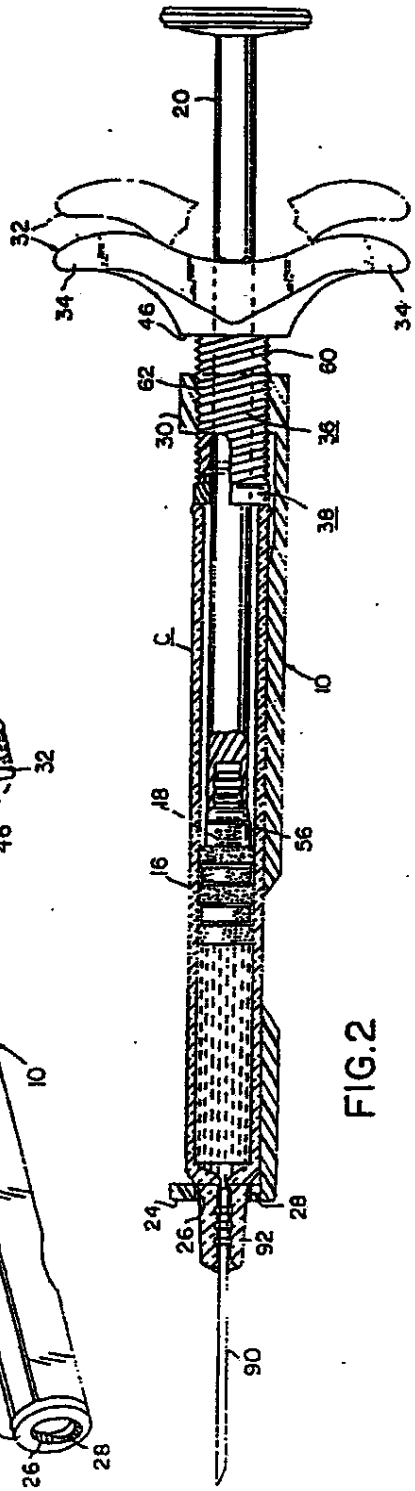


FIG.2

FIG.3

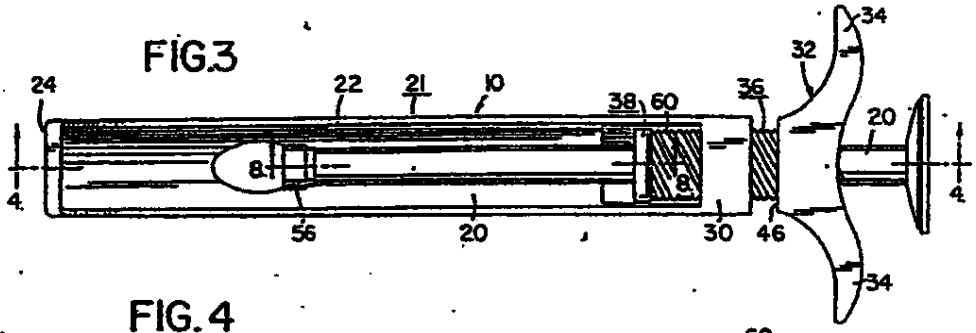


FIG. 4

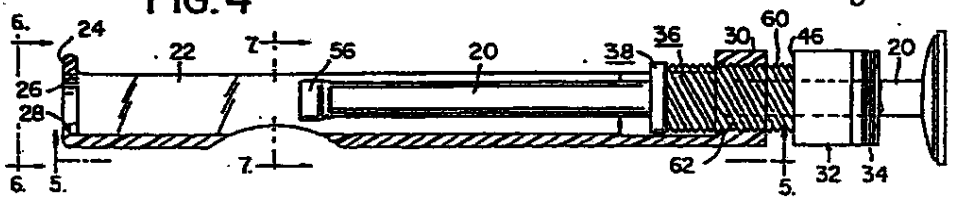


FIG.5

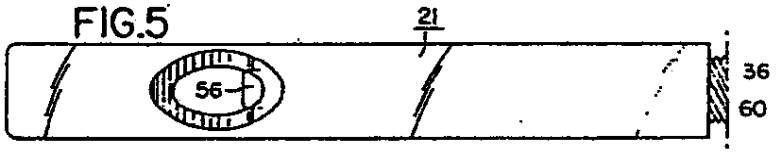


FIG.6

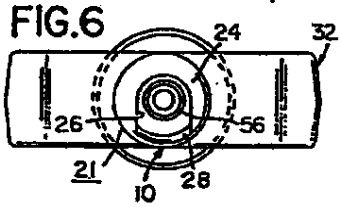


FIG. 7

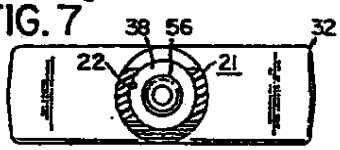


FIG.8

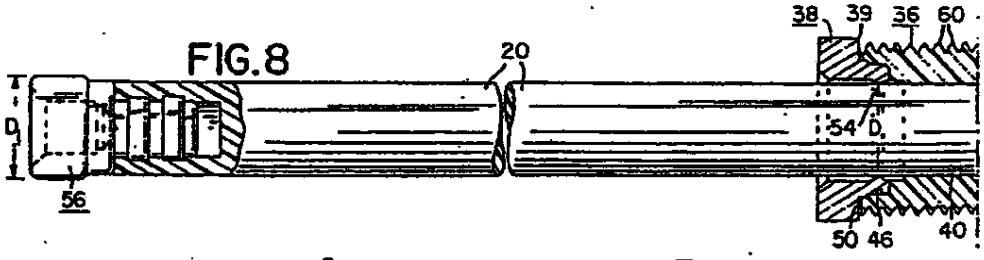


FIG.9

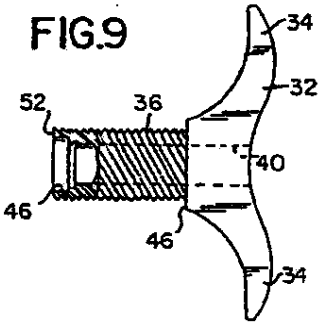


FIG.10

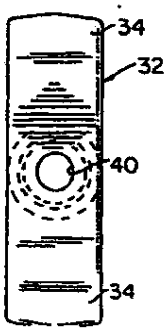


FIG.14

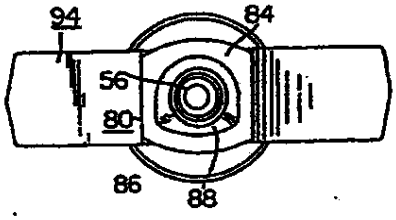


FIG.11

FIG.12

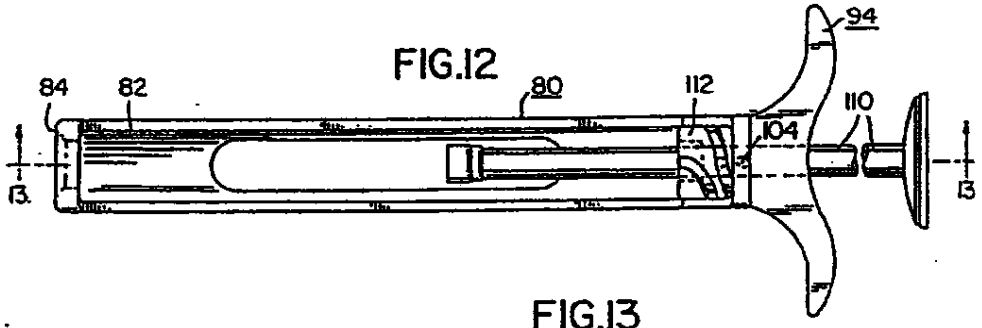


FIG.13

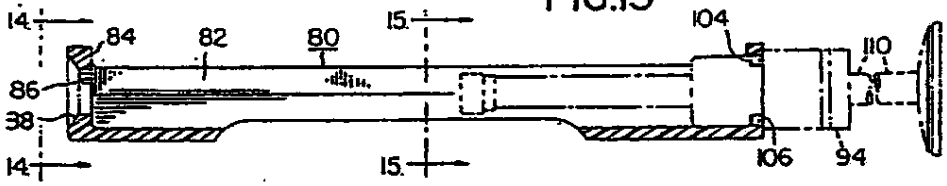


FIG.15

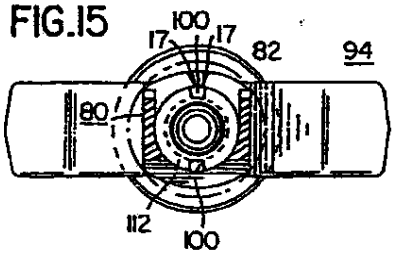
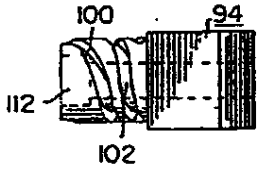


FIG.16



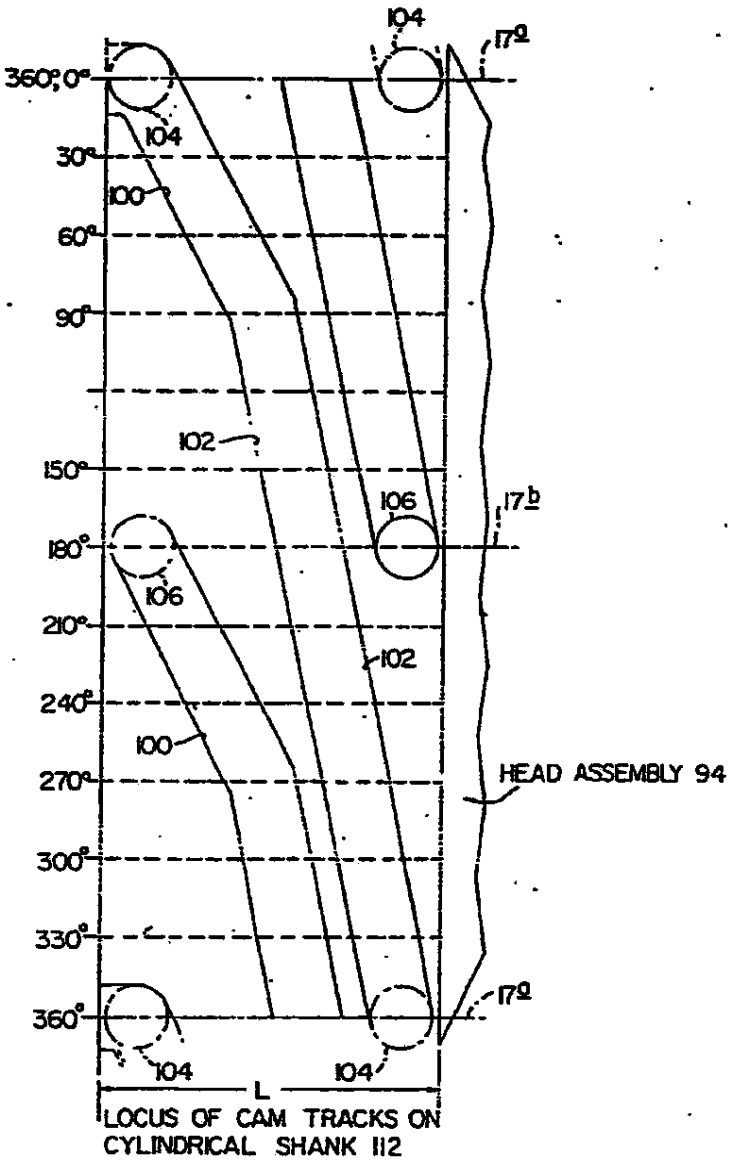

104
17a
360°, 0°
104
30°
100
60°
90°
102
150°
106
17b
180°
106
210°
102
240°
100
270°
HEAD ASSEMBLY 94
300°
330°
360°
17a
104
104
L
LOCUS OF CAM TRACKS ON
CYLINDRICAL SHANK 112

FIG.17

FAST ACTION CARTRIDGE SYRINGE HOLDER

FIELD OF THE INVENTION

The present invention relates to hypodermic syringe devices and more specifically to a reuseable syringe holder for use with disposable cartridges for medicaments in injectable form.

BACKGROUND OF THE INVENTION

Cartridge holders for dispensing parenteral pharmaceuticals by injection are not new per se. For example, the patents listed below show various forms of cartridge holders which are typical of prior art assemblies.

Inventor	Patent No.	Issue Date
Kasmauskas	1,546,491	July 21, 1925
Cook	Re. 16,836	Dec. 27, 1927
Brown	1,704,678	March 5, 1929
Smith	1,770,633	July 15, 1930
Nevin	1,819,258	Aug. 18, 1931
Debaz	2,829,643	April 8, 1958
Scroop	2,859,750	Nov. 11, 1958
Scroop	2,859,751	Nov. 11, 1958
Sarnoff	2,956,563	Oct. 18, 1960
Sarnoff	3,115,135	Dec. 24, 1963
Knight	3,556,099	Jan. 19, 1971
Baldwin	3,848,593	Nov. 19, 1974

Considering in some detail several of the above, Cook U.S. Pat. No. Re. 16,836 discloses a hypodermic syringe which locks a container or ampule 25 in barrel 10 by means of locking slots 19 in cap 17 engaging pins 18. This locking action is said to be the means by which the inner end of the needle punctures closure 26. (Page 1, lines 94 to 101)

Kasmauskas U.S. Pat. No. 1,546,491 shows a hypodermic syringe wherein a capsule 29 is locked between two shells 10 and 14. The relative movement of the shells to each other is both transverse and axial. Axial movement results by means of pin 17 cooperating with cam slot 18. The outer shell 14 is securely attached to the needle 28 while inner shell 10 is securely attached to head 13. Thus, as one shell is rotated with respect to the other, stopper 30 is punctured by the needle. (Page 1, lines 100 to 105)

Brown U.S. Pat. No. 1,704,678 discloses a hypodermic syringe wherein a glass cartridge tube 1 is locked in a tubular-like instrument body 7 by a screw cap 11. The finger supports appear to form a part of screw cap 11. Stopper 3 is pierced by pushing the cartridge onto the needle. The cartridge is pushed by an inwardly protruding portion bearing on the rear of the cartridge, which protruding portion is attached or a part of the screw cap 11 (Page 1, lines 91 to 104).

Debaz U.S. Pat. No. 2,829,643 is of interest in that the finger supports 11 are used as a clamping lever. Pivoting of the finger supports moves tensioning members 6 in an axial direction.

Knight U.S. Pat. No. 3,556,099, discloses a hypodermic syringe assembly wherein a cartridge is locked between two guide members 31 by plug 13. Plug 13 includes ridge portions 36. The plug is axially inserted in the syringe by passing ridges 36 in slots 29 until ridges 36 reach circumferential recesses 37, whereupon plug 13 is turned, moving ridges 36 into recesses 37. This axial movement of plug 13 acts to press on the cartridge, such that diaphragm 17 is pierced by needle 12. (Col. 4, lines 29-33) Alignment of finger grips 39 with grips 39' ensures that plug 13 is locked in place.

The various designs discussed above are of rather complicated construction and have certain functional disadvantages and drawbacks.

None of the patents disclose or suggest a holder providing ease of movement of the parts during assembly and disassembly of a spent cartridge and one providing excellent retaining forces when an axial load is present without the need for separate or retaining clamping members or the like.

SUMMARY OF THE INVENTION

These functional advantages are achieved in the holder of the present invention which is characterized by a novel arrangement of comparatively few parts so that the assembly is relatively economical to manufacture. Thus, the holder essentially comprises a head assembly and housing and novel means in the form of a multiple start screw mechanism for movably mounting the head assembly to the housing so that the parts are actuatable between an "open" position for insertion of a cartridge in the holder and a "closed" position firmly seating the cartridge in a position for administering the injectable product.

The advantages of this design over other previous disclosures is that it prevents a phenomenon known as "overhauling". Overhauling occurs when there is relative motion between the male and the female parts of the screw mechanism whereby the screw disengages or "falls through". Furthermore, the development of the optimum threading mechanism to prevent overhaul includes a specific matching of materials for the interengaging parts. These materials should have physical characteristics such that the frictional characteristics between the two interengaging parts are such that they provide ease of relative motion when there is no axial load applied and provide excellent retaining forces when an axial load is present. These characteristics include differences of hardness between the two materials, such difference being at least 5 on the Rockwell R Scale, and differences of coefficient of friction of at least 0.3. However, the function of this design is not restricted to those materials alone.

The plunger rod is a thermally formed injection molded tubular device commonly known in the medical field. The cartridge housing consists of a high clarity high impact resistant material capable of retaining the glass cartridges under any and all extraneous force applications in a secured and locked manner. The housing is clear such that the cartridge is clearly visible in any position and depth of engagement of the threaded "T" handle of the head assembly.

The "T" handle has two integral stops to prevent disassembly of the syringe holder while in use. The "T" handle is appropriately engaged to provide the maximum occurrence of cartridge visibility through the assembly port of the syringe cartridge body to enhance visibility.

The overall assembly of the housing with the "T" handle provides the required range to capture the open and closed cartridge systems currently known to the medical field. In the open system, the screw captures the cartridge assembly and in the closed systems, the holder first effects puncturing of a distal diaphragm by the proximal side of a double-ended needle assembly, then the screw captures the cartridge assembly.

The head assembly is of a predetermined novel configuration and arrangement to accommodate cartridges of varying lengths and, thus, the holder may be termed "universal".

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects of the present invention and the various features and details of the operation and construction thereof are hereinafter more fully set forth with reference to the accompanying drawings, wherein:

FIG. 1 is a perspective view of a cartridge syringe holder constructed in accordance with the present invention and two cartridge assemblies useable in present invention;

FIG. 1a is an enlarged fragmentary sectional view, taken on the line 1A, 1A of FIG. 1, showing details of a typical double ended needle, closed end cartridge assembly;

FIG. 2 is an enlarged sectional side elevational view of the cartridge syringe holder of this invention showing an open cartridge system mounted in an operative position therein;

FIG. 3 is a plan view of the cartridge syringe holder shown in FIG. 1;

FIG. 4 is a sectional side elevational view taken on the Line 4, 4 of FIG. 3 showing details of construction;

FIG. 5 is a fragmentary bottom plan view taken on the line 5, 5 of FIG. 4;

FIG. 6 is an end elevational view taken on the line 6, 6 of FIG. 4;

FIG. 7 is a transverse sectional view taken on the line 7, 7 of FIG. 4;

FIG. 8 is a greatly enlarged fragmentary side elevational view, with portions broken away and in section, taken on the line 8, 8 of FIG. 3, showing details of construction of the push rod and its associated stop ring and push rod tip;

FIG. 9 is a plan view of the head assembly with a portion broken away and in section showing certain details of construction;

FIG. 10 is a right hand end view of FIG. 9;

FIG. 11 is a perspective view of another embodiment of the cartridge holder in accordance with the present invention;

FIG. 12 is a plan view of the cartridge holder shown in FIG. 11;

FIG. 13 is a sectional side elevational view taken on the line 13, 13 of FIG. 12 showing details of construction and with the push rod and head assembly removed but shown in phantom outline;

FIG. 14 is an enlarged end view taken on the line 14, 14 of FIG. 13;

FIG. 15 is an enlarged transverse sectional view taken on the line 15, 15 of FIG. 13;

FIG. 16 is a side elevational view of the modified head assembly; and

FIG. 17 is a development of the cam slot arrangement for the holder embodiment shown in FIGS. 11–16, taken on the line 17, 17 of FIG. 15.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings and particularly to FIGS. 1–12 thereof, there is illustrated one embodiment of fast action cartridge holder in accordance with the present invention which is generally designated by the numeral 10. The holder 10 is adapted for use with cartridges C of various types and sizes for dispensing parenteral pharmaceuticals by injection. These cartridges typically comprise an elongated hollow tubular body portion 12 typically made of glass having a hypodermic needle 1a mounted at the discharge end of the body portion and a plunger 16 made of an elastomeric material fitted in the open outer end of the cartridge body. The plunger 16 mounts a threaded stud 18 for engagement by a plunger rod 20 of the holder assembly for actuating the plunger 16 axially toward the needle end to discharge the contents of the syringe when desired.

Considering now the holder assembly 10 and specifically the embodiment illustrated in FIGS. 1–12, the holder comprises an elongated housing 21 of generally U-shaped cross section defining an open slot 22 extending the length of the housing. The slot 22 facilitates insertion and removal of the cartridge in the housing in the manner described in more detail below. The lower end of the housing has an end wall 24 having an opening 26 through which the needle and lower end of the cartridge engage. The opening 26, as illustrated, is elongated and somewhat oval shaped and has a beveled, arcuate ramp portion 28 adjacent the closed end of the housing to serve as guide means when initially positioning the cartridge. The inner end of the housing 21 as illustrated has a circumferentially extending internally threaded collar 30 for mounting therein the fast action holder head assembly 32.

The head assembly 32 is mounted at the inner end of the housing 20 for axial movement relative to the collar 30. The head assembly 33 as best illustrated in FIGS. 3 and 6, is T-shaped in cross section having a pair of transversely extending wings 34, 34 with contoured inner surfaces engageable by the fingers of the use during use of the assembly to discharge the contents of the cartridge C. The head includes an elongated, externally threaded shank portion 36 having a stop ring 38 mounted in its outer end. The head assembly has an axially extending bore 40 for mounting an elongated plunger rod 42 therein. The stop ring 38 as illustrated has a shoulder 39 defining an abutment or inner limit position. As illustrated in FIG. 3, at the opposite end, the inner end of the housing 21 abuts the shoulder 46 between the head 32 and the shank 36.

The head assembly 32 is a two-piece arrangement wherein the stop ring 38 is press fitted in a bore 46 in the outer axial end of the shank 36. The stop ring, as best illustrated in FIG. 9, is of stepped configuration having a circumferentially extending bead 50 which seats against the axial end face 52 of the shank 36. The stop ring also has a circumferentially extending, internally radially inwardly directed bead 54 of a predetermined diameter to frictionally engage the push rod tip 56 and normally support it in a retracted position nested in the head assembly which facilitates assembly of the cartridge without interference from the plunger rod. Thus, the diameter D of the internal bead 54 of the stop ring is preferably smaller than the maximum diameter D_1 of the push rod tip 56 to facilitate this temporary positioning and gripping action. The plunger rod may be held in a retracted position by other means. For example, the plunger rod may be enlarged adjacent the tip portion to provide a slight interference fit in the bore of the shank when the plunger is moved to a fully retracted position. By this arrangement, when the plunger is advanced so that the enlarged portion of the plunger rod is disposed outside the shank bore, the plunger rod slides freely in the shank bore by reason of the normal clearance therebetween.

Other features of the holder of the present invention comprise a predetermined thread configuration between the shank and the collar portion which combine with the different materials between the two parts to produce quick actuation to seat the cartridge and a firm locking engagement between the head assembly and which produces a firm locking of the plunger under axial load without slippage or overhauling. The complementary threads 60, 62 of the shank 36 and collar 30 respectively are preferably a multi-start thread configuration and at least a three start thread configuration. For example, the thread specification may be as follows:

- ¾ UNF, 3 A modified thread
- 0.200 lead, 0.04 pitch
- 5 start thread
- Pitch diameter 0.3461-0.3490
- Major diameter 0.375

Consider now assembly and use of a cartridge in a holder made in accordance with the present invention. With the head assembly in a fully retracted position and with the plunger fully retracted, the parts are in position to receive a cartridge C. Note that the plunger rod stays in a retracted position when manipulating the assembly to seat a cartridge therein by reason of the frictional engagement of the plunger rod tip in the stop ring. This eliminates one moving part from interference in the assembly process. The needle end of a cartridge is then passed through the discharge opening with the cartridge slightly tilted. Note the entry ramp allows easy insertion of the cartridge during this phase of the assembly process. With the cartridge fully in place, and the assembly supported in one hand of the user, the user simply rotates the head assembly with the other hand until the stop ring abuts the end of the cartridge and firmly supports it in place. The plunger rod is then pushed inwardly and rotated to secure it to the threaded stud of the plunger and ready the syringe for use. After the cartridge is spent, the plunger is disassembled from the plunger and the head assembly retracted and the spent cartridge is easily removed from the open end of the housing.

As noted above, the fast-action and locking effect between the head assembly and collar is enhanced by making these two parts of two dissimilar materials. The whole housing 21 is most preferably made from a clear material so as to permit maximum visibility during loading, use and removal of the cartridges. The housing 21, in addition to being sufficiently transparent, must be impact resistant, easy and inexpensive to form and to machine, and must be compatible with all of the medical and hospital environments in which it is intended to be used. Preferred materials for the housing will comprise tough, machinable, heat resistant, transparent materials. Among these preferred materials are various thermoplastics which can be injection molded into the desired part configuration with or without machining to accurately define dimensions, shapes and tolerances.

Some of the polystyrene resins, for example, can be formed into housings which are clear, strong, resistant and machinable. Various families on the polycarbonate thermoplastic resins are also highly suitable materials for use in housings in accordance with this invention. One particular thermoplastic resin which is admirably suited for use as a material for the housing means of this invention is a polyphthalate carbonate copolymer manufactured by General Electric Company and sold under the trademark LEXAN®. Specifically, LEXAN®PPC 4501 polyphthalate carbonate copolymer resin is a preferred material for use as a material for the housing of the present invention. LEXAN®PPC 4501 is clear, heat and moisture resistant, hard and strong, and can be made with desired tolerances after being injection molded or otherwise formed into a desired shape. The resulting formed housing is hard and relatively smooth, having a coefficient of friction which is relatively low.

While the entire housing 21 is described as being hard, clear and resistant to environmental degradation, the collar 30 should also have a relatively low coefficient of friction. A low coefficient of friction allows the threads 62 of the collar 30 to cooperatively operate with the shank as hereinafter described in greater detail, so that the relative movement between the complementary threads 60 and 62 permits ease of relative motion when there is no axial load applied and also provide excellent retaining forces when an axial load is present. Accordingly, the material from which the collar is formed should have a relatively low coefficient of friction. Again, all of the materials described above as being suitable for the housing 21 are, of course, suitable for the collar 30 and the threads 62.

As has been stated, the threads 62 of collar 30 cooperate with the threads 60 of the shank 36. In order to achieve the cooperative functioning of the two parts, it is necessary that the collar 30 and shank 36, or at the very least the threads 62 and 60, be made from dissimilar materials. One of the materials, either for the shank or the housing, should be somewhat softer or more rubber-like and should have a higher coefficient of friction. When one part is harder and has a lower coefficient of friction with respect to the other, it has been found that there is, surprisingly, an ease of relative motion when there is no axial load applied and yet there is, again surprisingly, excellent retaining forces when an axial load is present. Since the two parts have relatively different hardness, there is no tendency or at least a substantially reduced tendency to form microwelds between the two contacting surfaces. Since the two parts have relatively different coefficients, there is ease of movement under no load and retaining forces when an axial load is present.

Because of the desire that the housing be hard and clear, for the reasons described above, it is preferred that the shank member 36 be formed from a softer material having a higher coefficient of friction. While many materials are suitable, it is preferred that the shank 36 be formed from thermoplastic materials which can be molded to a desired shape, machined or otherwise precision-shaped such as where the threads 60 are formed. Elastomeric resins which are relatively hard as elastomers and yet not as hard as materials from which the housing is formed, can be used to manufacture the shank of this invention Acrylonitrile butadiene styrene resins which have high gloss and median impact resistance are preferred choices for the shank material. A preferred material is an ABS resin manufactured by Monsanto Company under the trademark LUSTRAN®ABS 248 resin. Other materials having similar hardness and coefficient of friction properties are also suitable for this material.

It is, of course, possible to select materials in which the shank portion 36 is both harder and smoother than the housing 30. Because of the requirement that the housing be clear and resistant to impact, however, it is more practical to select a softer, higher coefficient of

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,744,790

DATED : May 17, 1988

INVENTOR(S) : Jankowski et al

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Claim 5, line 1; change the numeral "4" to —1—

Signed and Sealed this

Fourteenth Day of March, 1989

Attest:

Attesting Officer

DONALD J. QUIGG

Commissioner of Patents and Trademarks

friction material for the shank, and, in fact, the entire head assembly.

In either case, however, the relative relationship between the two parts 30 and 36, at least at the threads 62 and 60, should be such that there is a difference in hardness between them. Preferably, hardness differences should measure on the Rockwell R Scale of hardness of at least 5 and preferably from 8 to 30. Differences in hardness on the Rockwell R Scale of more than 30 are not as desirable. In one successful embodiment of this invention, the housing 21, including the collar 30 and threads 62 are formed from the previously referenced polyphthalate carbonated copolymer LEXAN@PPC 4501, which has a Rockwell R Scale hardness typically of 122. The shank 36 and thread 60 were formed from an ABS resin, LUSTRAN@ABS 248 resin, which had a Rockwell R Scale hardness typically of 112. Thus, the collar 30 is harder than the shank 36, as measured by Rockwell R Scale by 10 units on that scale. This is a preferred combination of dissimilar materials.

Similarly, the relative relationship between these same parts in their relative coefficient of friction properties also requires that there be a difference. Actual measurement of the coefficient of friction for molded parts and particularly for threads such as threads 60 and 62 is difficult and imprecise at best. Accordingly, the best way presently known to specify the relative relationship of the two surfaces and their respective coefficient of friction is that there, in fact, be a difference in coefficient of friction. Preferably the difference will be at least 0.1. Most preferred are materials where the difference in coefficient of friction between them ranges from 0.2 to 0.4.

The configuration and arrangement of the holder of the present invention provides certain functional advantages over the prior art. For example, with the particular thread configuration, the shank can be made comparatively long to thereby accommodate cartridges of various axial lengths without sacrificing speed of assembly. For example the head assembly can be fully seated over its maximum range with ease and with about only one and one-half turns. Further, the particular seating and nesting arrangement of the plunger rod tip facilitates assembly of cartridges without interference. In accordance with the configuration described, the shank and collar threads are always interengaged thereby ensuring good alignment at all times and this arrangement eliminates the possibility of cocking or jamming which is characteristic of some prior assemblies. Moreover, the use of the device to assemble the plunger is obvious to the user as compared with prior systems which utilize a separate screw element in the head assembly. Moreover, the transparent housing provides full visibility of the cartridge in any relative position of the head assembly and housing so that the user can observe blood flashback, air entrapment, particulate matter and other incompatibilities. In other words, at every relative angular position of the head and housing, there is always good visibility of the cartridge.

There is illustrated in FIGS. 13–20 another embodiment of holder assembly in accordance with the present invention. The holder, as illustrated, comprises an elongated housing 80 of generally U-shaped cross section having a longitudinally extending slotted opening 82 for inserting a cartridge C. At its outer terminal end, the housing has an end wall 84 with an opening 86 having a slanted discharge ramp 88 through which the needle 90 and hub portion 92 of the cartridge engage. In the present instance, means is provided connecting the head assembly 94 to the housing 80 to facilitate quick actuation of the head assembly between opposite limit positions during assembly and disassembly of a cartridge C. The means also provides automatic locking means when the head assembly has been rotated to a predetermined position exerting an axial load on a cartridge C mounted in the holder. This means comprises in the present instance, a series of cam slots 100, 102 and cam followers 104, 106 in the form of detents on the inner end of the housing which engage in the cam slots. The slot are of a preselected differing pitch to provide a quick advance during the initial actuation from a retracted position to seat the cartridge and then a more gentle slope in the latter stages of the seating process to provide a good locking action when an axial force is present to seat the cartridge in place in the housing. For example, the entrance cam slot 100 may be at an angle of about 25° to the axis of the shank and the locking cam slot portion 102 may be at an angle of about 10° to the axis of the shank. Similar to the previously described embodiment, the plunger rod 110 extends through the shank portion 112 of the head assembly and is frictionally retained therein and is normally disposed in a fully retracted position by friction engagement in the bore thereof.

The housing is also transparent to permit the user to read the dosage levels or recheck the medication and this is an advantage over prior art assemblies. Field studies have also shown that the users noted the reduction of steps from loading to locking as approximately one turn or less as providing an easy, convenient and time-saving assembly.

While a particular embodiment of the invention has been illustrated and described herein, it is not intended to limit the invention and changes and modifications may be made therein within the scope of the following claims. For example, the locking effect between the head assembly and shank may be enhanced by deliberately roughening the interfacing surfaces of the interengaging threads.

What is claimed is:

1. A holder for cartridges or containers for medicaments in injectable form comprising an elongated housing having a pocket for the cartridge, a head assembly including an elongated plunger rod adapted to be attached to the cartridge plunger for actuating the same to effect discharge of medicament from the cartridge, means operatively connecting the head assembly to one end of the housing for actuating a shank portion of the head assembly axially in the housing, said head assembly and housing having complementary threads having confronting thread surfaces and each surface having a different coefficient of friction to facilitate relative rotation of the head assembly and housing and resist slippage when the shank exerts an axial force on the cartridge to seat it in the housing.

2. The device of claim 1, wherein said head assembly and said housing are made from different materials whereby the hardness of one material with respect to the other is at least 5 units higher on the Rockwell R Scale hardness test.

3. The device of claim 2, wherein said housing is made from the harder material.

4. The device of claim 3, wherein the difference in Rockwell R Scale hardness is from about 10 to about 20 units.

5. The device of claim 4, wherein said head assembly and said housing are made from different materials

whereby the coefficient of friction of one material with respect to the other is at least 0.1.

6. The device of claim 5, wherein said housing has the lower coefficient of friction.

7. The device of claim 6, wherein the difference in coefficient of friction is from about 0.2 to about 0.4.

8. The device of claim 4, wherein said head assembly is made from an ABS resin and the housing is made from a polyphthalate carbonate copolymer resin.

9. The device of claim 7, wherein said head assembly is made from an ABS resin and the housing is made from a polyphthalate carbonate copolymer resin.

10. A holder for cartridges or containers for medicaments in injectable form comprising an elongated housing having a pocket for the cartridge, a head assembly including an elongated plunger rod adapted to be attached to the cartridge plunger for actuating the same to effect discharge of medicament from the cartridge, means operatively connecting the head assembly to one end of the housing for actuating a shank portion of the head assembly axially in the housing between a retracted and extended position, said head assembly and housing being made of dissimilar materials to facilitate relative rotation of the head assembly and housing and resist slippage when the shank exerts an axial force on the cartridge to seat it in the housing, and means for detachably locking the plunger rod in a retracted position.

11. A holder as claimed in claim 10, wherein the bead assembly includes a stop ring and wherein the internal diameter of a bead of the stop ring is smaller than maximum diameter of the push rod tip.

12. A holder for cartridges or containers for medicaments in injectable form comprising an elongated housing having a pocket for the cartridge, a head assembly including an elongated plunger rod adapted to be attached to the cartridge plunger for actuating the same to effect discharge of medicament from the cartridge, means operatively connecting the head assembly to one end of the housing for actuating a shank portion of the head assembly axially in the housing, said means comprising a series of cam slots and detents on the inner side of the housing engageable in the cam slots, said slots being of a predetermined differing pitch to provide a quick advance during initial actuation from a retracted position and a more gentle slope to provide secure locking action, said head assembly and housing being made of dissimilar materials to facilitate relative rotation of the head assembly and housing and resist slippage when the shank exerts an axial force on the cartridge to seat it in the housing.

13. A holder for cartridges as claimed in claim 10, wherein said housing is made of a clear plastic material.

14. A holder for cartridges as claimed in claim 10, wherein said head assembly is of a t-shaped cross section including a pair of transversely extending wings for actuating the threaded shank portion to lock a cartridge in place and also for use in discharging contents of the cartridge.

* * * * *

United States Patent [19]

Hoffman et al.

[11] Patent Number: 4,990,142

[45] Date of Patent: Feb. 5, 1991

[54] HYPODERMIC SYRINGE

[75] Inventors: J. Kenneth Hoffman, Warren, Pa.; Joseph W. Blake, III, New Canaan, Conn.

[73] Assignee: GTE Products Corporation, Stamford, Conn.

[21] Appl. No.: 425,253

[22] Filed: Oct. 23, 1989

[51] Int. Cl.[5] A61M 5/00

[52] U.S. Cl. 604/232

[58] Field of Search 604/232, 187, 234, 218

[56] References Cited

U.S. PATENT DOCUMENTS

3,115,135 12/1963 Sarnoff ..... 604/232 X

FOREIGN PATENT DOCUMENTS

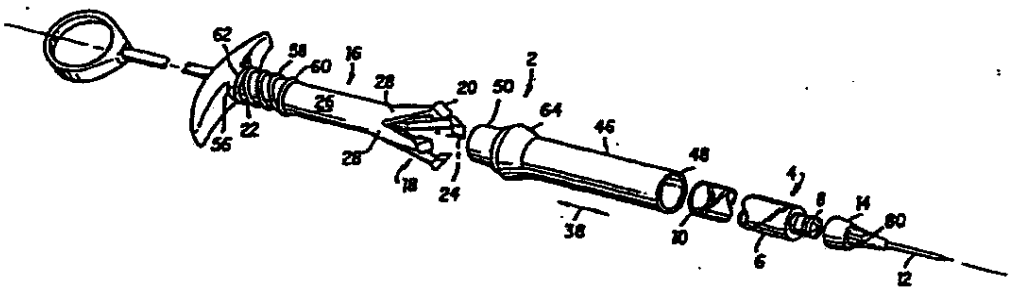
562017 5/1960 Belgium 604/232

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—William H. McNeill

[57] ABSTRACT

An inner elongated tubular member having a plurality of arms which extend from one end thereof and a concentric outer sleeve slideable relative to the tubular member for urging each of the arms into engagement with the hub of a needle attached to one end of a medicament cartridge to lock the cartridge and its needle to the tubular member and form a hypodermic needle.

6 Claims, 3 Drawing Sheets



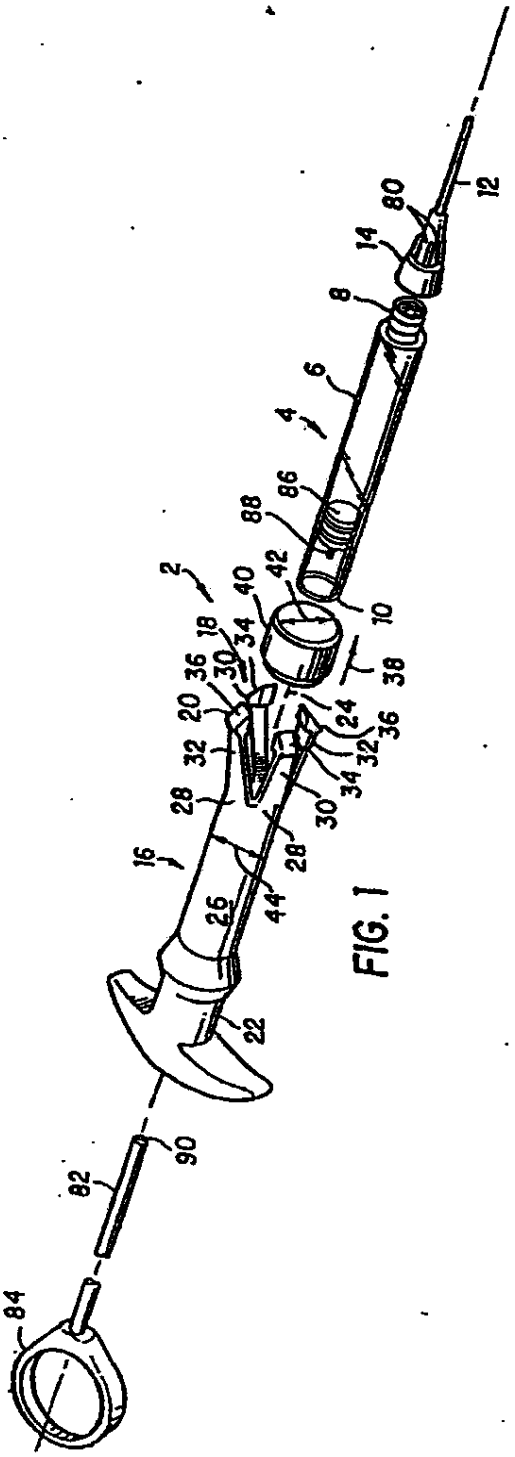

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FIG. 1

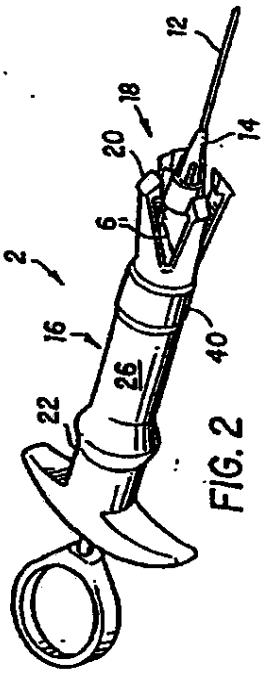
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FIG. 2

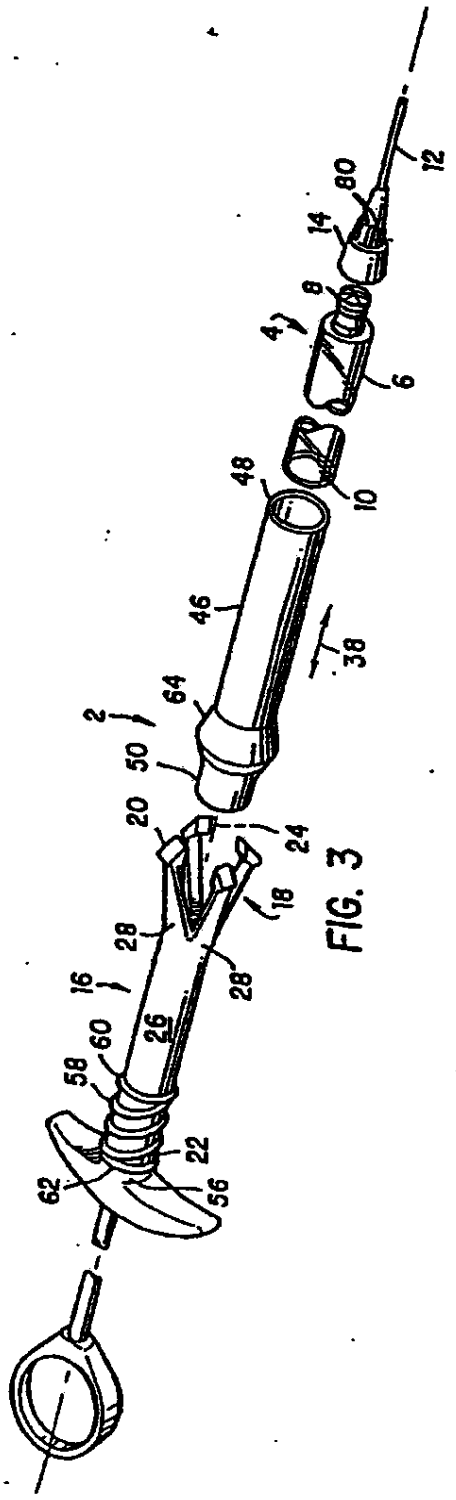


FIG. 3

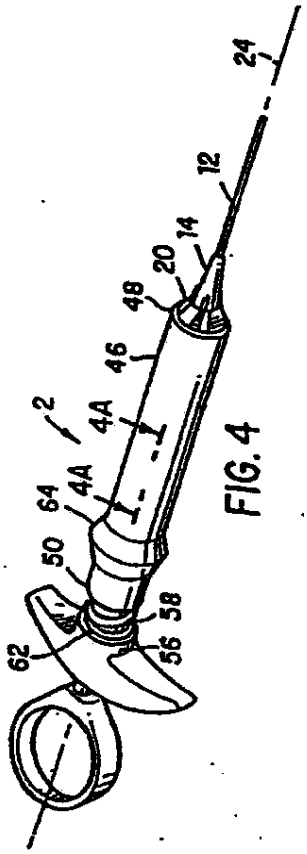


FIG. 4

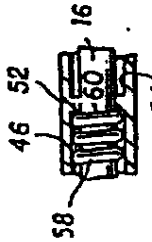
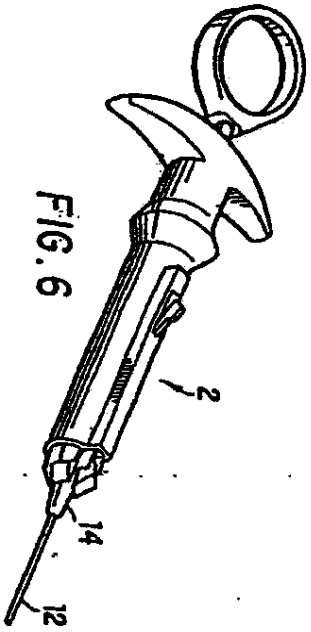


FIG. 4A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12

FIG. 6

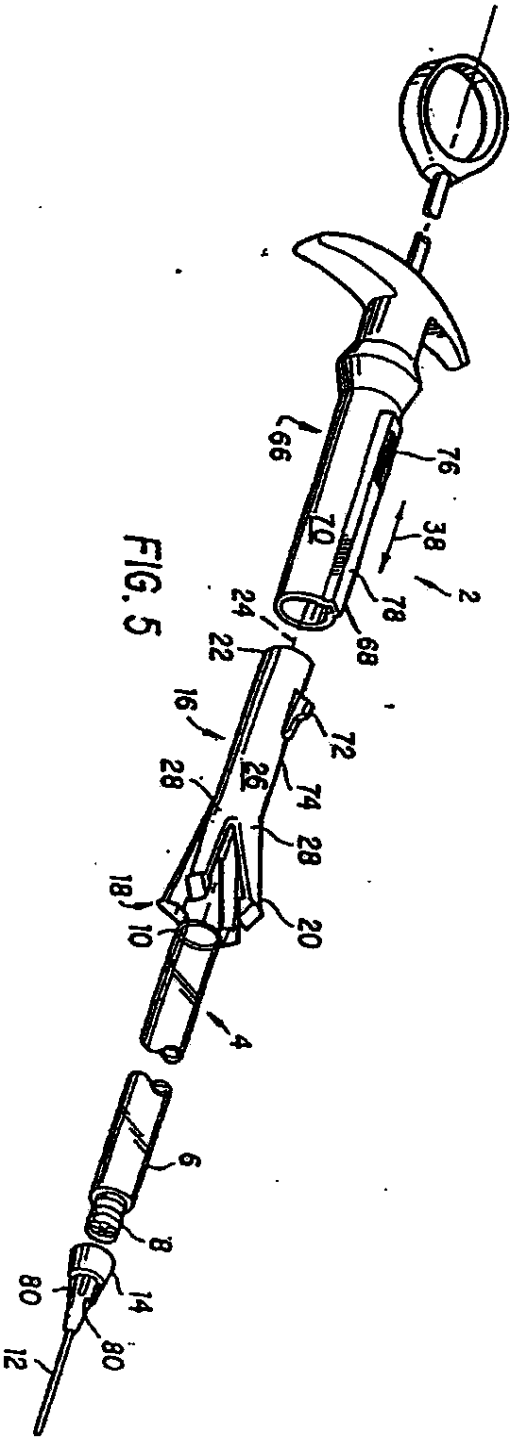
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FIG. 5

HYPODERMIC SYRINGE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a device for holding a cartridge having a needle attached thereto and for dispensing medicament from the cartridge or drawing blood into the cartridge. When coupled together, the holding device, cartridge and needle form a hypodermic syringe.

2. Description of the Prior Art

One form of hypodermic syringe typically includes a generally cylindrical barrel including a piston rod therein. The rod includes a handle at one end to facilitate reciprocating movement of the rod within the cylindrical barrel. In such a hypodermic syringe a cartridge is provided having a needle attached thereto, the cartridge being inserted into the cylindrical barrel to work in combination with the piston rod to dispense or receive liquid such as medicament or blood, respectively, in response to movement of the piston rod within the barrel. In this form of syringe the piston rod is connected to a plunger in the inserted cartridge, axial movement of the piston rod causing corresponding axial movement of the plunger to dispense the medicament from the cartridge or receive blood within the cartridge depending upon whether such movement is a dispensing movement or aspirating movement. Such hypodermic needles are well known in the art and examples include embodiments described in U.S. Pat. Nos. 2,524,367 to Smith and 4,744,790 to Jankowski et al.

One problem that occurs during use of such a hypodermic syringe is that of accidental exposure of the user of the syringe to whatever contaminants might be present upon or within the needle or cartridge after use thereof. For example, in those instances where the needle and cartridge are to be removed from the barrel and disposed of, heretofore it has been necessary for the user to grasp the needle to remove the needle and cartridge assembly from the barrel. Such grasping can expose the attendant to any contaminant which is on the exterior surface of the needle and cartridge, particularly if the attendant is not wearing a glove. In addition, not infrequently the attendant might be accidentally punctured by the needle while attempting to remove the needle and cartridge and corresponding contamination of the user will obviously result. Somewhat related to these problems is the not unlikely possibility that the attendant might drop the needle and cartridge assembly while removing the assembly from the barrel structure resulting in undesirable contamination of the area exposed to the needle and cartridge. A similar problem is the possibility that the needle and cartridge assembly might prematurely fall out of the barrel-like holder during the disposal operation. In any event, accidental contamination of a medical attendant or anyone else can present a serious health problem especially if the contaminant is an infectious disease such as hepatitis, AIDS and the like.

In order to prevent undesirable contamination, it is highly desirable to provide a hypodermic syringe wherein a medical attendant can remove a cartridge and needle assembly from an associated holder without grasping or otherwise touching the assembly. Similarly, it is also desirable to provide a hypodermic syringe wherein a medical attendant can remove such an assembly without the assembly prematurely falling out of the holder as a result of the attendant carelessly attempting to grasp the assembly and without the attendant inadvertently dropping the assembly.

SUMMARY OF THE INVENTION

This invention achieves these and other results by providing apparatus for use with a cartridge to form a hypodermic syringe. The cartridge includes an elongated body having a first end and a second end and having a needle attached to the first end by means of a hub which is attached to one end of the needle. The device comprises an elongated tubular member having one end which includes a plurality of arms extending therefrom and an opposite other end. The arms are moveable in a radial direction relative to a longitudinal axis of the elongated tubular member and are resiliently biased away from the longitudinal axis. The elongated tubular member is configured such that the cartridge is insertable into the elongated tubular member at the second end of the cartridge until the hub is adjacent the plurality of arms and the needle is extending from the elongated tubular member in the direction of the longitudinal axis. Means is positioned around the elongated tubular member and is slidable relative to the elongated tubular member in the direction of the longitudinal axis, for urging each arm of the plurality of arms towards the longitudinal axis, and into locking engagement with the hub when the cartridge has been inserted into the elongated tubular member, as the means is moved towards the one end and engages the plurality of arms. Means is associated with the elongated tubular member for dispensing and aspirating the hypodermic syringe which is formed when the cartridge is inserted into and coupled to the elongated tubular member.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of one embodiment of the present invention;

FIG. 2 is an assembled perspective view of the embodiment of FIG. 1 in an open or unlocked position;

FIG. 3 is an exploded perspective view of another embodiment of the present view;

FIG. 4 is an assembled perspective view of the embodiment of FIG. 3 in a closed or locked position;

FIG. 4A is a sectional view taken along 4A–4A of FIG. 4;

FIG. 5 is an exploded perspective view of yet another embodiment of the present invention; and

FIG. 6 is an assembled perspective view of the embodiment of FIG. 5 in a closed or locked position.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The embodiments of this invention which are illustrated in FIGS. 1 to 6 are particularly suited for achieving the objects of this invention. FIGS. 1 to 6 depict apparatus for use with a cartridge to form a hypodermic syringe 2. The cartridge 4 includes an elongated body 6 which is preferably glass. Body 6 includes a first end 8, a second end 10 and a needle 12 which is attached to first end 8 by means of a hub 14 which is attached to one end of the needle in a known manner.

An elongated tubular member 16 is also provided having one end 18 which includes a plurality of arms 20 extending therefrom and an opposite other end 22. The elongated tubular member 16 is preferably polycarbonate. The individual arms which comprise the plurality

of arms 20 are moveable in a radial direction relative to a longitudinal axis 24 of the elongated tubular member 16 and are resiliently biased away from longitudinal axis 24 as depicted in FIGS. 1, 3 and 5. The elongated tubular member 16 is configured such that the cartridge 6 can be inserted into member 16 at second end 10 of the cartridge, the cartridge being inserted to the point where the hub 14 is adjacent the plurality of arms 20 and the needle 12 extends from the member 16 in the direction of the longitudinal axis 24, as depicted in FIGS. 2, 4 and 6.

In the preferred embodiment the elongated tubular member 16 and the plurality of arms 20 are formed by a unitary structure. In such structure, the member 16 includes a body portion 26, and each of the plurality of arms 20 is integrally hinged to the body portion 26 and extends at an angle away from the body portion at a respective hinge 28, as depicted in FIGS. 1, 3 and 5. In the preferred embodiment, the plurality of arms 20 comprises two pairs of opposing arms, such as, for example, the first pair of opposing arms 30 and the second pair of opposing arms 32 depicted in FIG. 1. In the embodiment depicted in the drawings the plurality of arms 20 comprise two pairs of opposing claw-like arms. For example, as depicted in FIG. 1, opposing arms 30 include claw-like ends 34 and opposing arms 32 include claw-like ends 36. Preferably, each arm of the plurality of arms 20 is circumferentially spaced at about ninety degrees from an adjacent arm, as depicted in FIGS. 1, 3 and 5.

Means is positioned around the elongated tubular member 16 and is slidable relative to member 16 in the direction of longitudinal axis 24 for urging each arm of the plurality of arms 20 radially towards axis 24 as such means is moved towards end 18 and engages the plurality of arms. In this manner the arms of the plurality of arms 20 will be urged into locking engagement with the hub 14 in those instances when the cartridge has been inserted into the elongated tubular member 16 and such means has been moved in the direction of the arrow 38. In the preferred embodiment, a body portion 26 is provided which is cylindrical and an urging means is provided in the form of a polypropylene sleeve having an inner diameter which is greater than an outer diameter of the body portion. Such a configuration facilitates sliding movement of the sleeve relative to the body portion along longitudinal axis 24. For example, in the embodiment depicted in FIGS. 1 and 2, body portion 26 is cylindrical and the urging means is a sleeve 40 having an inner diameter 42 which is greater than outer diameter 44 of body portion 26 to facilitate sliding of the sleeve 40 relative to the body portion 26. In the embodiment of FIGS. 1 and 2 the length of sleeve 40 is less than the length of the body portion 26 measured in the direction of the axis 24.

Referring to FIG. 2, it will be readily apparent that by sliding sleeve 40 towards end 18 of the elongated tubular member 16 the inner surface of sleeve 40 will engage the arms of the plurality of arm 20 and by virtue of a camming action urge the arms radially towards the axis 24 into locking engagement with hub 14 to thereby lock the hub and its needle in place vis-a-vis the elongated tubular member to form the hypodermic syringe 2. The subsequent sliding of sleeve 40 in the opposite direction towards end 22 will allow the arms to move radially away form axis 24 and disengage the hub 14 due to the resiliency and original angular orientation of the arms. In this manner the cartridge can be removed from the elongated tubular member without the attendant touching the cartridge or needle.

In the alternative embodiment of FIGS. 3, 4 and 4A, an elongated sleeve 46 is provided. Sleeve 46 is preferably polypropylene. Sleeve 46 includes an end 48 adjacent the plurality of arms 20 and an opposite end 50. Referring to FIG. 4A, the sleeve further includes a first rest 52 which extends from an inner surface 54 of the sleeve 46. The elongated tubular member 16 in FIGS. 3, 4, and 4A is preferably polypropylene and includes a second rest 56 at end 22 of member 16. A stainless steel compression spring 58 is provided, spring 58 being externally concentric with elongated tubular member 16 and internally concentric with sleeve 46 as depicted in FIG. 4A. A first end 60 of spring 58 bears against the first rest 52 and a second end 62 of the spring bears against the second rest 56. Means is provided for facilitating sliding movement of the sleeve 46 relative to the elongated tubular member 16 in the direction of longitudinal axis 24. For example, in the embodiment depicted in FIGS. 3 and 4, an outwardly expanding section 64 of the sleeve 46 is provided.

In the operation of the embodiment of FIGS. 3, 4 and 4A, the sleeve 46 can be grasped at the section 64 and caused to move in the direction of longitudinal axis 24 towards rest 56 by compressing spring 58 between rests 52 and 56. Such movement will cause the plurality of arms to move radially away from axis 24 as depicted in FIG. 3 due to the resiliency and original angular orientation of the arms. Such movement of the arms provides access to the interior of the elongated tubular member 16, and the cartridge 4 can therefore be inserted therein until the hub 14 is adjacent the arms. When the cartridge is so positioned, releasing of the section 64 will allow spring 58 to decompress causing the sleeve to move along axis 24 towards end 18 of member 16. Such movement causes a camming action between the sleeve 46 and the arms 20 which urges the arms in a radial direction towards axis 24 and into locking engagement with the hub 14 as depicted in FIG. 4.

In the alternative embodiment of FIGS. 5 and 6, an elongated sleeve 66 is provided including a keyway 68 which extends in the direction of longitudinal axis 24 and outward from outer surface 70 of the sleeve. Body portion 26 of the elongated tubular member 16 includes a corresponding key 72 which extends from outer surface 74 of the body portion. Preferably, the elongated sleeve 66 and elongated tubular member 16 are polypropylene. When the body portion 26 is inserted into the sleeve 66 the key 72 mates with the keyway 68 to facilitate sliding movement of the sleeve relative to the elongated tubular member along axis 24. As in the embodiments of FIGS. 1 to 4A, a camming action of the sleeve relative to the arms moves the arms in a radial direction for engagement with, and the locking in place of, the cartridge. In the embodiment depicted in FIGS. 5 and 6, the keyway 68 includes aperture 76 through a surface 78 thereof, and key 72 is in the form of a resilient locking tab which mates with aperture 76 in a locking position when the plurality of arms 20 have been urged towards axis 24 as depicted in FIG. 6. Preferably, the locking tab 72 and elongated tubular body member 16 are formed by a unitary structure. Depression of the tab allows for movement of the member 16 away from the sleeve 66 so that the resilient arms spring outward relative to the axis 24 to thereby unlock the cartridge 16.

In the embodiments depicted in the drawings each cartridge 4 includes a hub 14 which includes at least

one, and preferably a plurality, of recessed areas 80 and the plurality of arms 20 include corresponding arms which mate with such areas when the cartridge has been inserted into the elongated tubular member 16 and the arms have been urged into locking engagement with the hub as discussed herein. For example, in the embodiment of FIGS. 1 and 2, claw-like ends 34 and 36 mate with recessed areas 80 of hub 14. Hub 14 can be formed from any suitable material but is preferably metal such as stainless steel.

All of the embodiments of FIGS. 1 through 6 include means associated with the elongated tubular member 16 for dispensing and aspirating the hypodermic syringe 2 which is formed when cartridge 4 is inserted into and coupled to the member 16. For example, and by way of example only, the embodiment of FIG. 1 is depicted as including a piston rod 82 having a handle 84 at one end to facilitate reciprocating movement of the rod in a known manner. Similarly, cartridge 4 includes a typical plunger 86 therein which is coupled to the piston rod 82 in a known manner such that axial movement of the piston rod causes corresponding axial movement of the plunger to dispense the medicament from the cartridge or receive blood within the cartridge depending upon whether such movement is a dispensing movement or aspirating movement. Piston rod 82 and handle 84 are preferably formed from acetal. In the embodiment of FIG. 1 the piston rod 82 can be coupled to plunger 86 by means of the threaded protuberance 88 and corresponding threaded bore 90. In the embodiments described herein each apparatus can include the section 64 to facilitate operation of the hypodermic syringe when the apparatus is assembled and ready for use.

The preferred materials for forming the embodiments of the present invention have been discussed herein. However, the apparatus of the present invention can be formed from any material useful in the manufacture of hypodermic syringes. If desired various components can be transparent so that the content of the cartridge 4 can be viewed. For example, in FIG. 1 the elongated tubular member 16 can be transparent.

It will be readily apparent that the present invention provides a hypodermic syringe wherein a medical attendant can remove a cartridge assembly including a needle attached thereto from a holder without grasping or otherwise touching such assembly and without such assembly falling out of the holder as a result of the attendant carelessly attempting to grasp the assembly and without the attendant inadvertently dropping the assembly.

The embodiments which have been described herein are but some of several which utilize this invention and are set forth here by way of illustration but not of limitation. It is apparent that many other embodiments which will be readily apparent to those skilled in the art may be made without departing materially from the spirit and scope of this invention.

We claim:

1. Apparatus for use with a cartridge to form a hypodermic syringe, said cartridge including an elongated body having a first end and a second end and having a needle attached to said first end by means of a hub which is attached to one end of said needle, comprising:

an elongated tubular member having one end which includes a plurality of arms extending therefrom and an opposite other end, said arms being moveable in a radial direction relative to a longitudinal axis of said elongated member and being resiliently biased away from said longitudinal axis;

said elongated tubular member being configured such that said cartridge is insertable into said elongated tubular member at said second end of said cartridge until said hub is adjacent said plurality of arms and said needle is extending from said elongated tubular member in the direction of said longitudinal axis;

said elongated member and said plurality of arms being formed by a unitary structure, said elongated tubular member including a body portion, and each arm of said plurality of arms being integrally hinged to said body portion and extending at an angle away from said body portions at a respective hinge;

urging means positioned around said elongated tubular member and being slidable relative to said elongated tubular member in the direction of said longituinal axis, for urging each arm of said plurality of arms towards said longitudinal axis, and into locking engagement with said hub when said cartridge has been inserted into said elongated member, as said means is moved towards said one end and engages said plurality of arms;

said body portion being cylindrical and further wherein said urging means comprises a sleeve having an inner diameter greater than an outer diameter of said body portion to facilitate sliding movement of said sleeve relative to said body portion along said longitudinal axis;

said sleeve being elongated and including an end adjacent said plurality of arms and an opposite end, said sleeve further including a first rest extending from an inner surface of said elongated tubular member and located between said end and said opposite end, wherein said opposite other end of said elongated tubular member includes a second rest, and further including a compression spring externally concentric with said elongated tubular member and internally concentric with said sleeve, a first end of said compression spring bearing against said first rest and a second end of said compression spring bearing against said second rest;

and means associated with said elongated tubular member for dispensing and aspirating said hypodermic syringe which is formed when said cartridge is inserted into and coupled to said elongated tubular member.

2. The apparatus of claim 1 further including means associated with said sleeve for facilitating sliding of said sleeve in the direction of said longitudinal axis.

3. The apparatus of claim 2 wherein said facilitating means includes an outwardly expanding section of said sleeve.

4. The apparatus of claim 3 wherein said plurality of arms comprises two pairs of opposing arms.

5. The apparatus of claim 4 wherein said plurality of arms comprises two pairs of opposing claw-like arms.

6. The apparatus of claim 5 wherein each arm of said plurality of arms is circumferentially spaced at about ninety degrees from an adjacent of said arms.

* * * * *

United States Patent [19]

Holm et al.

[11] Patent Number: 4,973,318

[45] Date of Patent: Nov. 27, 1990

[54] DISPOSABLE SYRINGE

[75] Inventors: Niels E. Holm, Birkerød; Allan Spork, Lyngby; Klaus Thogersen, Klampenborg; Anders Bressendorff, Virum; Jorn Rex, Roskilde, all of Denmark

[73] Assignee: D.C.P. AF 1988 A/S, Denmark

[21] Appl. No.: 308,399

[22] Filed: Feb. 9, 1989

[30] Foreign Application Priority Data

Feb. 10, 1988 [DK] Denmark 692/88

[51] Int. Cl.[5] A61M 5/00

[52] U.S. Cl. 604/208; 604/211; 604/218

[58] Field of Search 604/206, 207, 208, 209, 604/210, 211, 187, 232, 236, 246, 248, 192, 263, 71, 72, 186, 218

[56] References Cited

U.S. PATENT DOCUMENTS

1,997,129	4/1935	Taylor et al.	
2,605,763	8/1952	Smoot	
2,695,023	11/1954	Brown	
2,718,299	9/1955	Atwater et al.	
2,826,195	3/1958	Ashkenaz	
3,138,157	6/1964	Ziherl et al.	604/71
3,348,545	10/1967	Sarnoff et al.	
3,517,668	6/1970	Brickson	
3,790,048	2/1974	Luciano et al.	
3,894,663	7/1975	Carhart et al.	
3,905,366	9/1975	Callahan et al.	
3,977,574	8/1976	Thomas	
4,022,207	5/1977	Cizin	
4,099,548	7/1978	Sturm et al.	
4,103,684	8/1978	Ismach	604/71
4,244,366	1/1981	Raines	
4,246,898	1/1981	Travalcat et al.	
4,275,729	6/1981	Silver et al.	
4,395,921	8/1983	Oppenlander	
4,413,760	11/1983	Paton	
4,415,101	11/1988	Shapiro et al.	
4,457,712	7/1984	Dragan	
4,470,317	9/1984	Sablocwski et al.	
4,475,905	10/1984	Himmelstrup	
4,498,904	2/1985	Turner et al.	
4,583,973	4/1986	Humphrey et al.	604/218
4,583,978	4/1986	Porat et al.	
4,592,745	6/1986	Rex et al.	

FOREIGN PATENT DOCUMENTS

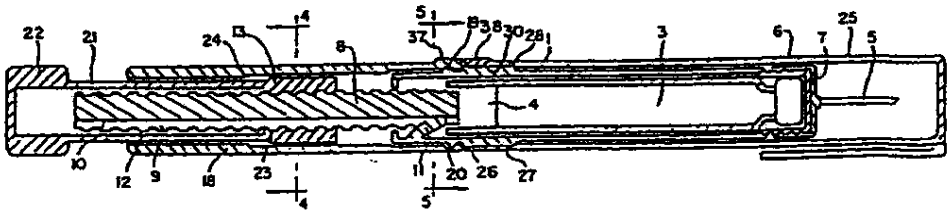
0037696	4/1960	European Pat. Off.
0064858	5/1981	European Pat. Off.
0143895	8/1984	European Pat. Off.
0226718	12/1985	European Pat. Off.
730971	1/1943	Fed. Rep. of Germany
1149735	12/1957	France
1170312	1/1959	France
1445659	6/1966	France
CH84/00167	6/1985	PCT Int'l Appl.
CH86/00151	5/1987	PCT Int'l Appl.
WO88/07374	10/1988	PCT Int'l Appl.
293302	12/1953	Switzerland
991766	5/1965	United Kingdom
1145483	3/1969	United Kingdom
1225495	3/1971	United Kingdom
2109690	2/1982	United Kingdom

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Willian Brinks Olds Hofer Gilson & Lione

[57] ABSTRACT

A disposable syringe includes first and second housing elements which are coupled together for rotation without axial movement therebetween. The first housing element receives a cartridge of a solution to be injected, and mounts a liquid outlet needle at its front end. A piston rod is disposed in the second housing element to move axially therein, and this piston rod includes a rod element and a nut element. The rod element is coupled to the first housing element to move axially therein without relative rotation therewith, and the nut element is threaded to the rod element for telescoping movement therewith and is configured to move axially in the second housing element without relative rotation therein. A pressure receiving element is mounted on the nut element. The housing, rod, nut and pressure receiving elements cooperate such that relative rotation between the housing elements in a selected direction causes relative rotation between the nut and rod elements and thereby increases the effective length of the piston rod and causes the pressure receiving element to extend from the second housing element. A protective cap is removably mounted over the first housing element and is configured to abut second housing element while mounted in place on the first housing element. This protective cap is engaged with the first housing element such that rotation of the cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

30 Claims, 9 Drawing Sheets



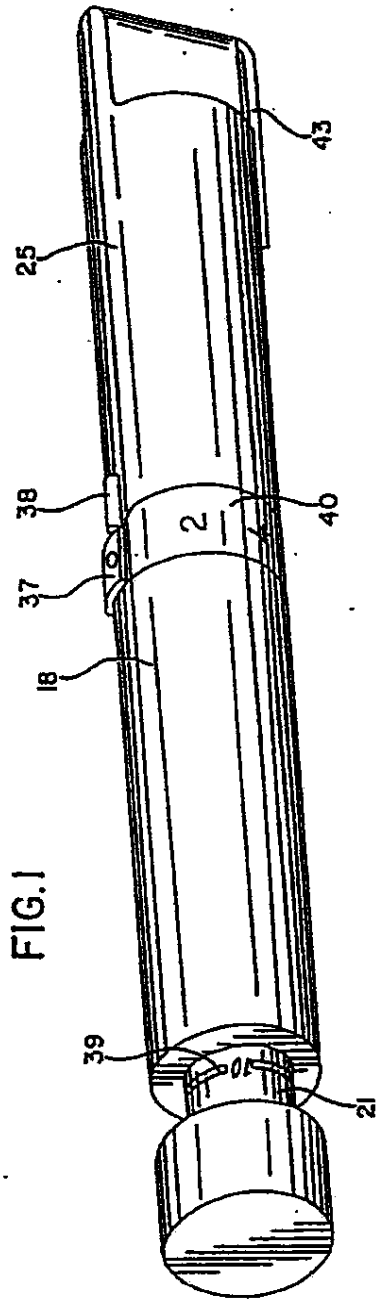


FIG. 1

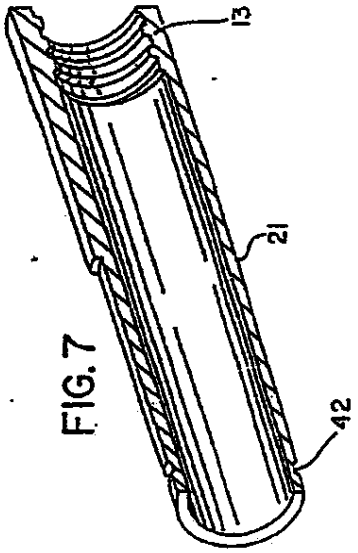


FIG. 7

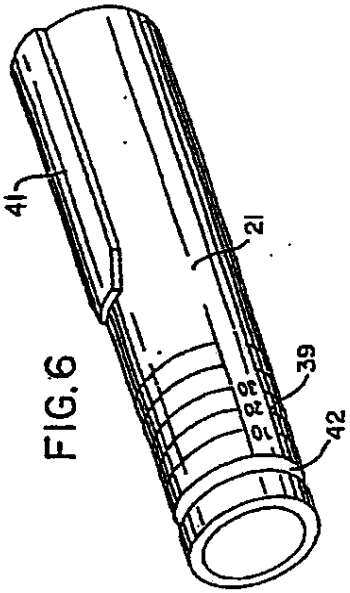


FIG. 6

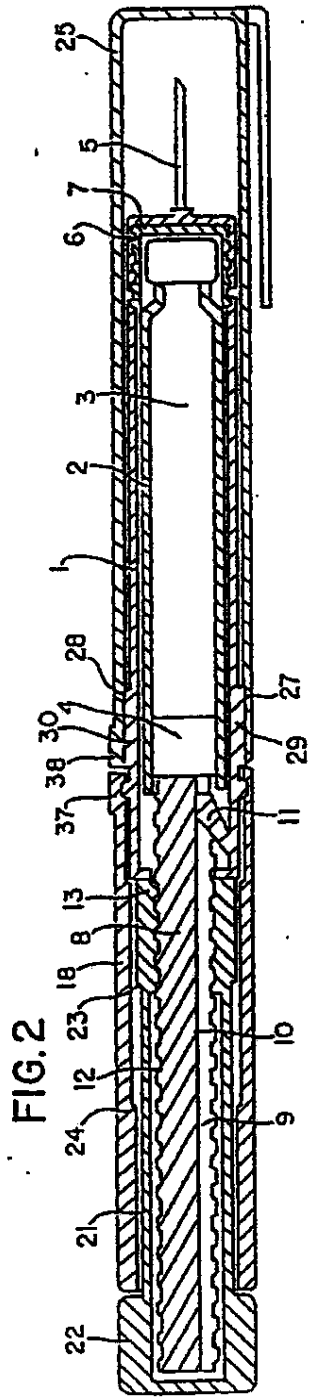


FIG. 2

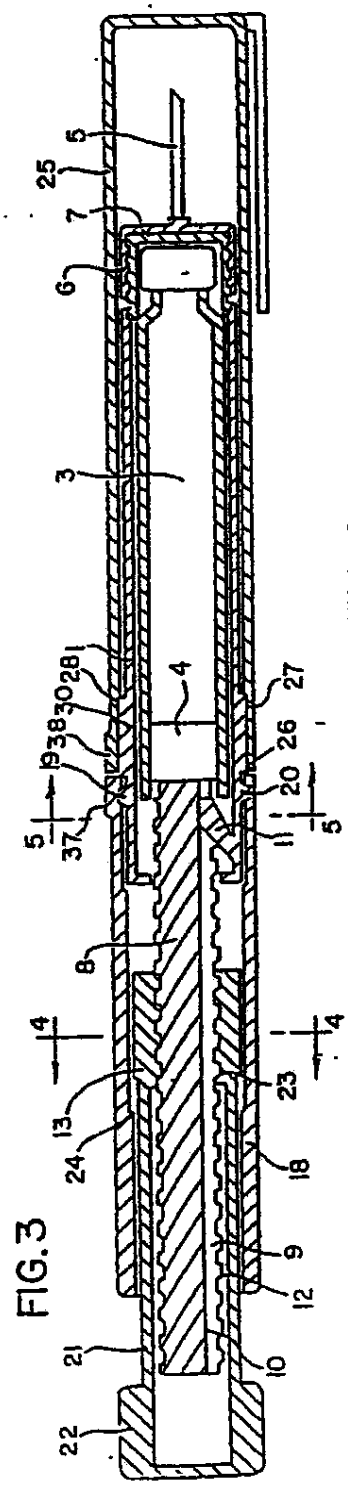


FIG. 3

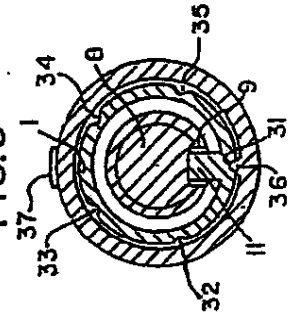


FIG. 5

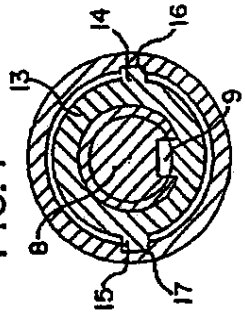


FIG. 4

FIG. 8

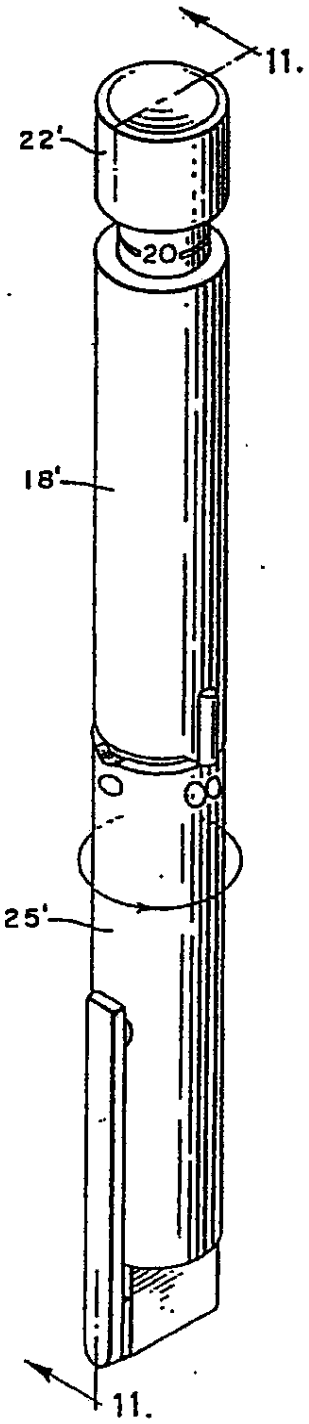


FIG. 9

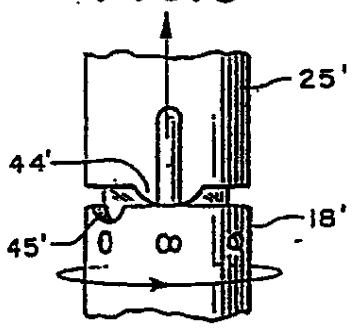


FIG. 10

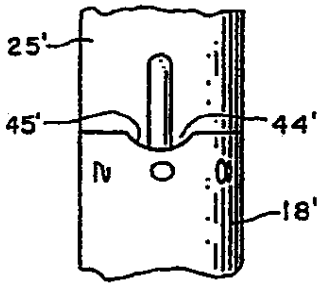


FIG. 12

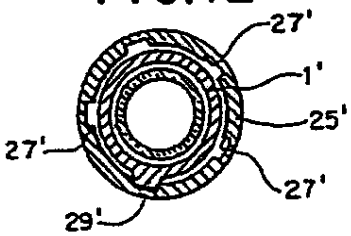


FIG. 13

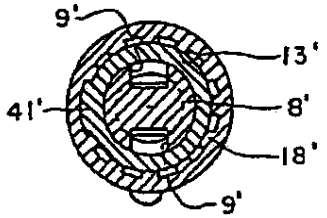
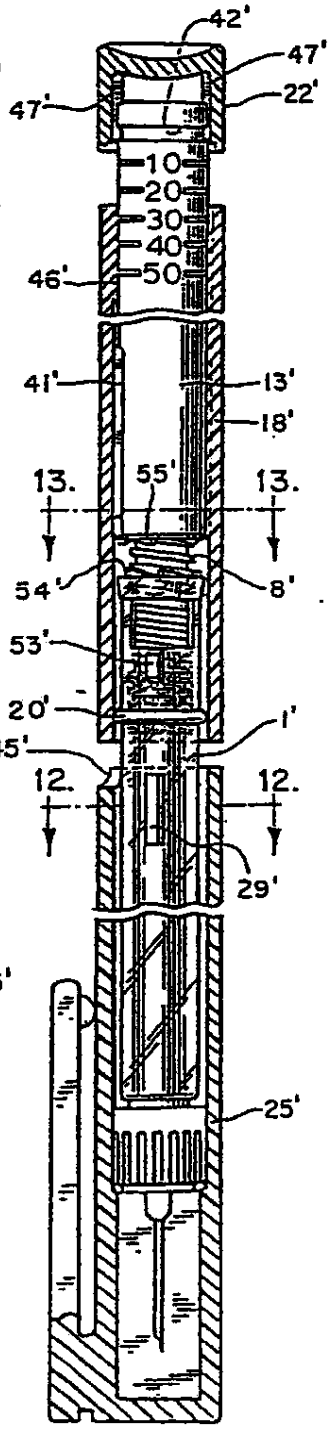


FIG. 11



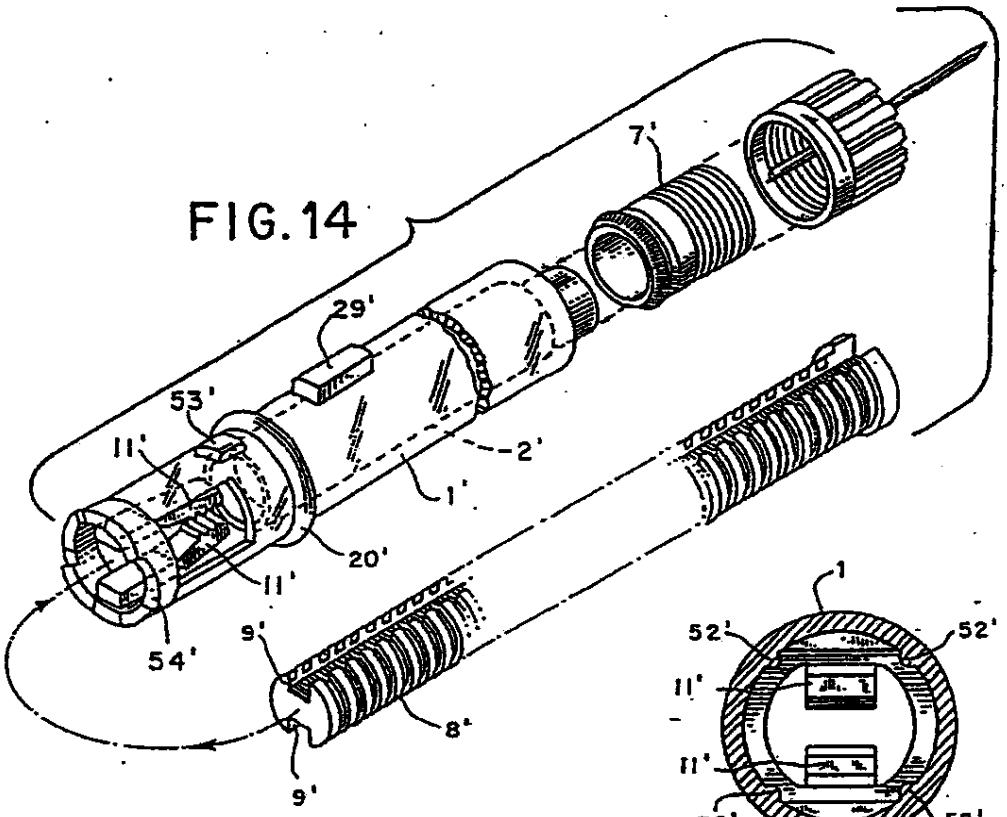


FIG. 14

FIG. 16

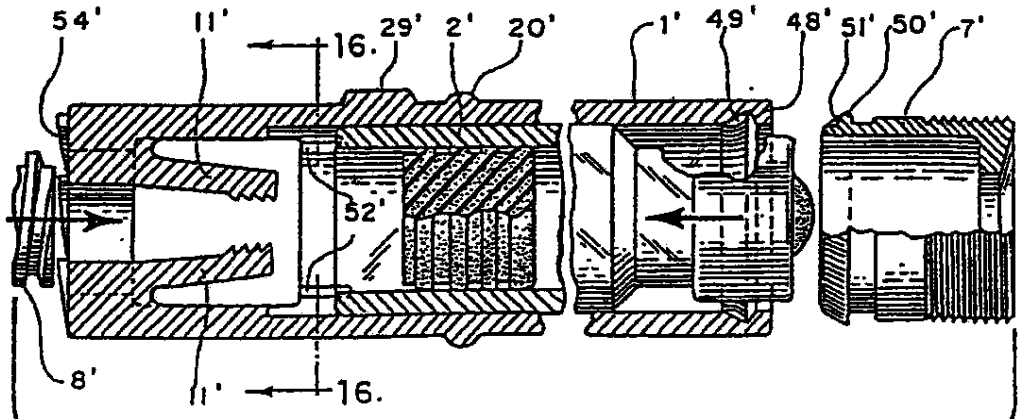


FIG. 15

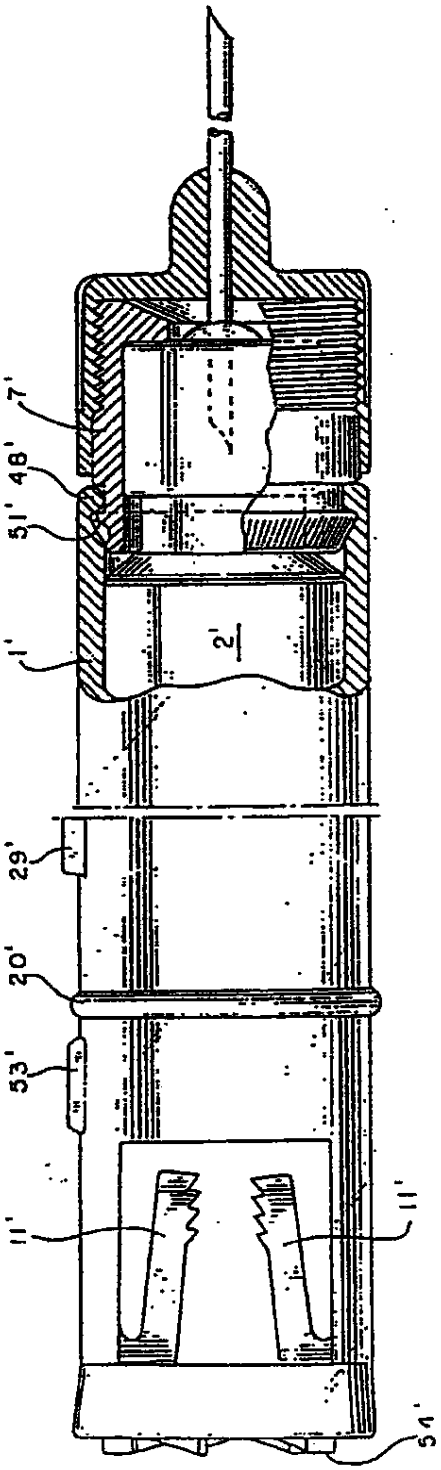


FIG.17

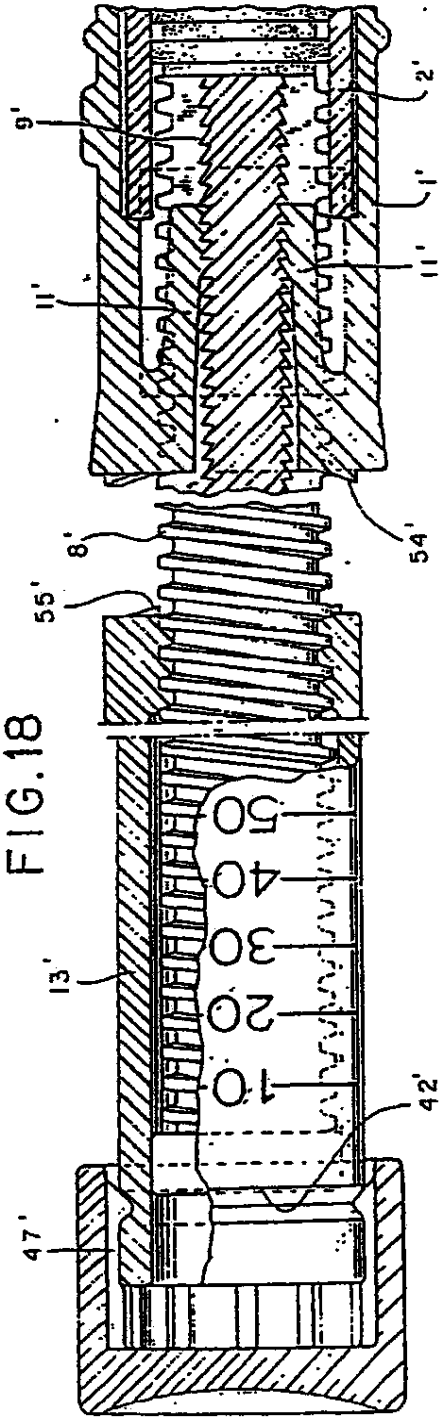


FIG.18

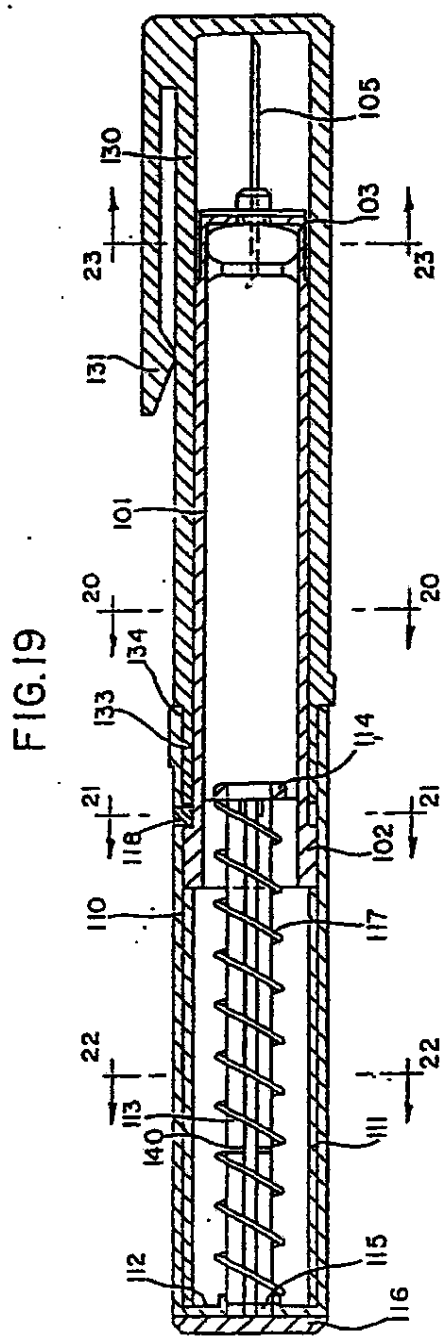

105
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FIG. 19

FIG. 20.

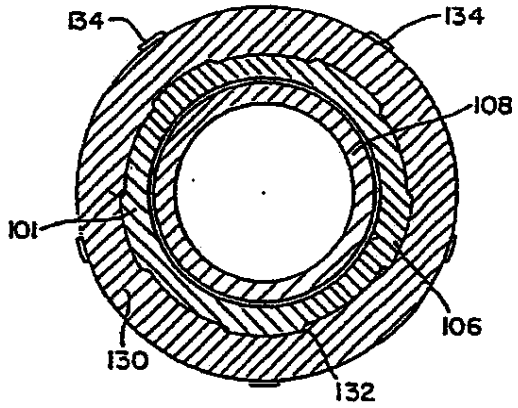


FIG. 21

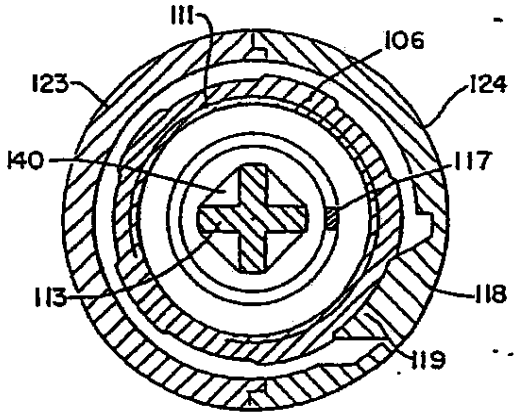


FIG. 22

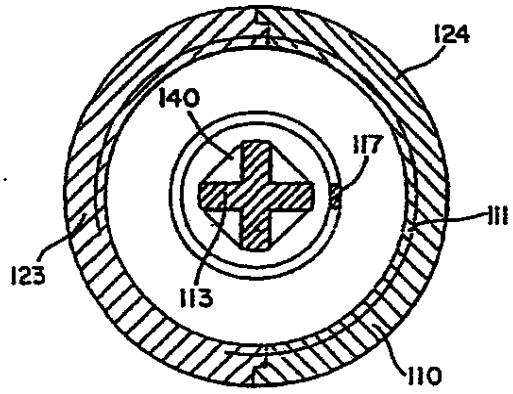
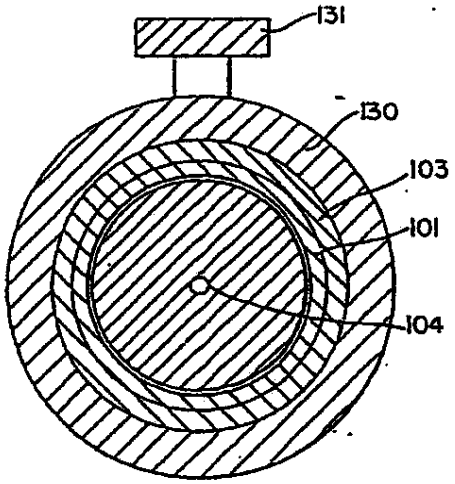


FIG. 23



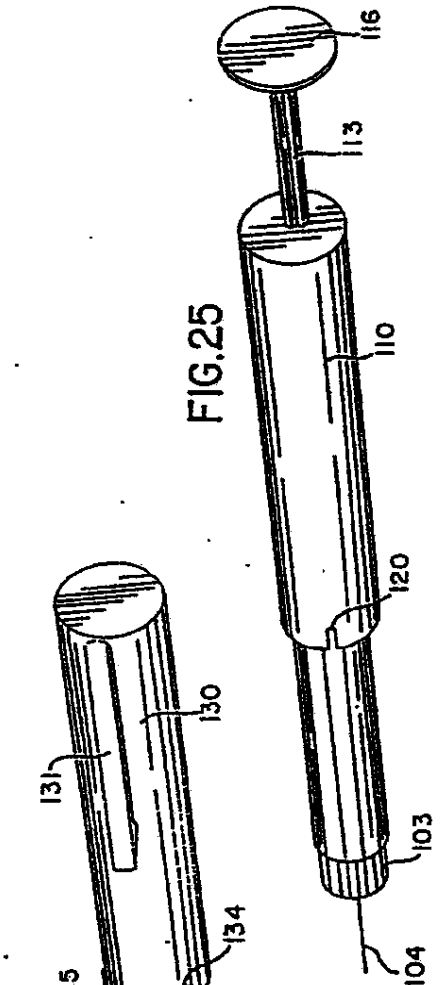


FIG.25

FIG.24

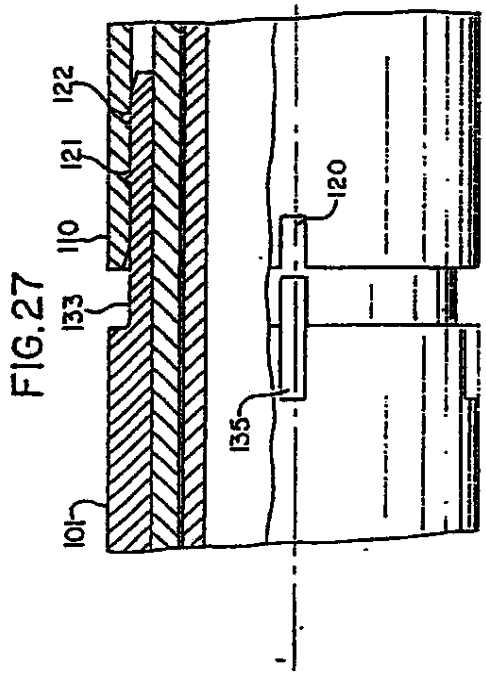


FIG.27

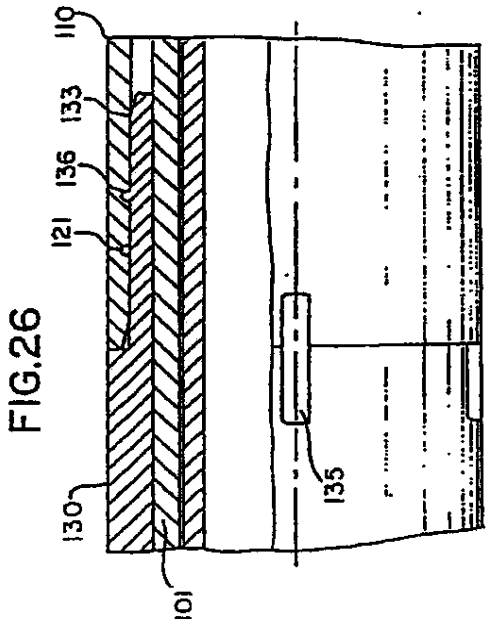


FIG.26

DISPOSABLE SYRINGE

TECHNICAL FIELD

This invention relates to a disposable syringe for injecting preset doses of a liquid contained in the syringe. The syringe of this invention is particularly but not exclusively applicable for delivering preset dosages of insulin, and the following description relates to a device for the injection of insulin solutions. However, it is to be understood that the syringe of this invention is also suitable for the injection of preset dosages of other liquids.

In particular, this invention relates to a syringe or dosage unit of the type that comprises first and second housing elements coupled together to allow rotation of the first housing element with respect to the second housing element, wherein the first housing element is adapted to receive a quantity of liquid and comprises means for mounting a liquid outlet needle in the front end thereof, and wherein the second housing element has a rear end situated opposite the front end of the first housing element.

BACKGROUND ART

Diabetics have to inject themselves repeatedly with insulin solution, and the volume of insulin solution to be injected may vary from injection to injection. For this reason, diabetics need syringes which allow them to inject successive measured dosages of the same or different preset volumes of insulin solution.

A wide variety of syringes have been proposed. For example, International Patent publication No. WO 82/02662 discloses a dose metering device for use with a syringe. The metering device utilizes a manually rotatable cap which axially moves the piston in the syringe. The volume delivered by the syringe is determined by the angular stroke of the cap. This device is not fully satisfactory for use by diabetics, because it requires two hands to hold the syringe and rotate the cap. For this reason, a diabetic cannot use this device to inject insulin into a skin fold, as recommended by many physicians.

Another drawback of the above-mentioned dose metering device is that production costs are so high that in practice it must be re-used. This necessitates replacement of the syringe or at least a cartridge with a new one. During the reloading operation, dust or other contaminants may be introduced into the metering device and this may adversely affect the operation of the metering device. Furthermore, there are more and more different commercially available insulin preparations, and therefore there is an increasing risk that a patient may insert a syringe or cartridge containing an insulin preparation other than the required one. Furthermore, reloading requires a series of operations which although not complicated may yet be troublesome for the patient.

It is therefore an object of this invention to provide a syringe that is so simple and inexpensive that it can be discarded after use.

Another object of this invention is to provide a syringe capable of delivering a number of accurate preset doses without reloading.

A further object of the invention is to provide a syringe which can be used for a single handed operation, with preadjustment of the total quantity to be injected.

A further object of the invention is to provide a syringe of such dimensions that it can be carried in a pocket like a writing pen.

Yet another object of this invention is to provide a dosage unit that maintains a constant length in use.

SUMMARY OF THE INVENTION

According to a first aspect of this invention, a disposable syringe of the type described above comprises a piston rod disposed in the second housing element to move axially therein. This piston rod comprises a rod element and a nut element. The rod element is coupled to the first housing element to move axially therein without relative rotation therebetween; and the nut element is threaded to the rod element for telescoping movement therewith and is configured to move axially in the second housing element without relative rotation therebetween. A pressure receiving element is mounted on the nut element, and the housing, rod, nut and pressure receiving elements all cooperate such that relative rotation between the housing elements in a selected direction causes relative rotation between the rod and nut elements and thereby increases the effective length of the piston rod and causes the pressure receiving element to extend from the second housing element. In this way, a measured quantity of the liquid is expressed from the needle when the pressure receiving element is moved back toward the second housing element.

Preferably, the nut element defines an axial scale along its length and is used in combination with the second housing element to gauge the dosage of liquid to be administered. As described below, the first and second housing elements may be arranged to rotate with respect to one another without axial movement therebetween such that the first and second housing elements maintain a substantially constant overall length as liquid is progressively dispensed through the needle.

The disposable syringe described below is easily preadjusted to the desired dose and quantity by rotating the two housing elements with respect to one another. This causes the nut element to move along the rod element and the pressure receiving element to be axially displaced. The indicator or scale connected to the nut element thereby moves with respect to the second housing element, and the scale can be used to measure the quantity of liquid that will be dispensed when the pressure receiving element is pushed back toward the second housing element. When the pressure receiving element is pushed back to its initial position, the nut element engages the rod element and the rod element is prevented from rotating relative to the first housing element. For this reason, axial movement of the nut element results in movement of the rod element. Preferably, a ratchet device is installed between the first housing element and the rod element to insure that the rod element cannot be retracted once it is pushed into the first housing element.

The following detailed description describes a number of other advantageous features of the invention. For example, the nut element preferably comprises at least one radially protruding, axially extending projection on the outside of the nut element which slides in an associated axially extending groove of the inner surface of the second housing element. Preferably, the nut element is shaped to limit axial movement of the nut element out of the second housing element beyond the predetermined limit, and in this way to prevent the dosage unit from being adjusted to deliver a potentially dangerously high

dose of liquid. In the preferred embodiment described below, the nut element and the indicator on the nut element are integrally formed together, thereby minimizing the total number of parts and the cost of the system. In this embodiment the nut element is substantially axially symmetrically shaped, and the pressure receiving element at the external end of the nut element has an outer diameter that corresponds to the outer diameter of the second housing element. As a result, the axial movement of the nut element towards the distal or rear end of the second housing element is stopped in a simple manner.

This embodiment utilizes a rod element that is prevented from rotating relative to the first housing element by means of a ratchet device. As discussed below, at least one and preferably two pawls are provided on the first housing element, and these pawls engage longitudinal grooves in the rod element, which are provided with a suitable toothed configuration to cooperate with the pawls.

According to a second feature of this invention, a disposable syringe or dosage unit, which may, for example, be of the type described above, includes a protective cap that is removably mounted over the front end of the first housing element to protect the needle. Means are provided for releasably coupling the protective cap and the first housing element for rotation together such that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

Preferably, the protective cap is configured to receive the first housing element such that a front portion of the second housing element substantially abuts a rear portion of the protective cap when the protective cap is mounted in place on the first housing element. In the preferred embodiment described below, the abutting ends of the cap and the second housing element together comprise a scale for measuring relative rotation of the protective cap with respect to the second housing element. This scale allows the rotational position of the cap with respect to the second housing element, and therefore the dose to be injected, to be gauged precisely. The scale formed at the abutting ends of the cap and the second housing element indicates the rotational position of the cap in fractions of a full rotation, while the measuring scale associated with the nut element described above indicates the number of full rotations of the cap with respect to the second housing element.

In the preferred embodiment described below, the cap may be releasably engaged with the first housing element at any one of a number discrete rotational positions, and a plurality of detents are provided at corresponding increments of rotation of the first housing element with respect to the second housing element. With this arrangement it is always possible to situate the measuring scale portion of the cap opposite a fixed zero on the second housing element such that this zero position forms the basis for measuring rotation of the cap with respect to the second housing element. This is possible regardless of the detent position of the first housing element with respect to the second element, and it provides the important advantage that the user of the syringe is provided with a clear zero position at the start of each adjustment. This feature instills confidence in the user that the desired dosage has in fact been selected.

The invention itself, together with further objects and attendant advantages, will best be understood by reference to the following detailed description, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a first preferred embodiment of a dosage unit according to the invention, said dosage unit being ready for injection of a predetermined quantity of liquid.

FIG. 2 is an axial sectional view of the dosage unit of FIG. 1 before the adjustment of a predetermined dosing quantity.

FIG. 3 is an axial sectional view through the dosage unit of FIG. 1.

FIG. 4 is a sectional view taken along line 4—4 of FIG. 3.

FIG. 5 is a sectional view taken along line 5—5 of FIG. 3.

FIG. 6 is a perspective view of an embodiment of an indicator integrally formed with an associated nut member, with portions removed for the sake of clarity.

FIG. 7 is an axial sectional view of the nut member of FIG. 6.

FIG. 8 is a perspective view of a second preferred embodiment of a dosage unit or disposable syringe according to this invention.

FIG. 9 is a partial view of the syringe FIG. 8, showing the cap positioned to allow rotation of the cap with respect to the second housing element of the syringe.

FIG. 10 is a view corresponding to FIG. 9 showing the cap seated in its zero position against the second housing element.

FIG. 11 is a longitudinal sectional view taken along line 11—11 of FIG. 8.

FIG. 12 is a cross-sectional view taken along line 12—12 of FIG. 11.

FIG. 13 is a cross-sectional view taken along line 13—13 of FIG. 11.

FIG. 14 is an exploded perspective view of components of the syringe of FIG. 8.

FIG. 15 is an exploded breakaway longitudinal sectional view of selected components of FIG. 14.

FIG. 16 is a cross-sectional view taken along line 16—16 of FIG. 15.

FIG. 17 is a side view in partial cut-away of selected components of FIG. 14 in the assembled position.

FIG. 18 is a longitudinal sectional view of components of the syringe of FIG. 8.

FIG. 19 is a longitudinal sectional view of a third embodiment of a dosage unit according to this invention.

FIG. 20 is a cross-sectional view taken along the line 20—20 of FIG. 19.

FIG. 21 is a cross-sectional view taken along the line 21—21 of FIG. 19.

FIG. 22 is a cross-sectional view taken along the line 22—22 of FIG. 19.

FIG. 23 is a cross-sectional view taken along the line 23—23 of FIG. 19.

FIG. 24 is a perspective view of the syringe of FIG. 19, showing the cap partially removed.

FIG. 25 is a perspective view of the syringe of FIG. 19, showing the cap fully removed.

FIG. 26 is a partial longitudinal sectional view of the syringe of FIG. 19, showing the cap fully inserted into the second housing element.

FIG. 27 is a view corresponding to FIG. 26 showing the cap partially removed from the second housing element.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1–7, 8–18 and 19–27 relate to first, second, and third embodiments of this invention, respectively. The first and second embodiments embody both aspects of the invention described above, while the third embodiment embodies only the second aspect of the invention.

Turning to FIGS. 1–7, the first embodiment comprises a first housing element or casing 1 for a cartridge 2 containing a liquid 3. The cartridge 2 comprises a piston 4 pressing the liquid 3 out through a needle 5 inserted in the opposite end, said needle being secured to the casing 1 in a generally known manner by screwing on of a cup-shaped cap 6. As indicated in FIGS. 2 and 3, the cartridge 2 can be retained in the casing by means of a retaining cap 7 optionally secured to the casing by a snapping effect. The retaining cap 7 allows introduction of a protruding end of the needle 5, said end optionally extending into the interior of the cartridge. This introduction and insertion of the needle 5 is preferably carried out during the screwing on of the needle-carrying cap 6 onto the retaining cap 7 of the casing 1.

At the end opposite the needle 5 the dosage unit comprises a piston rod member 8 driving the piston 4 in the cartridge 2. This piston rod member 8 comprises a longitudinal groove 9 provided in the bottom with transverse barbs 10, and the groove 9 is serrated when seen in a longitudinal section (FIG. 3). These barbs cooperate with a pawl 11 formed on the casing 1. The pawl 11 is provided with barbs which cooperate with the barbs 10 on the piston rod member 8. These barbs 10 and the pawl 11 are shaped so as only to allow displacement of the piston rod member 8 towards the piston 4 of the cartridge and to prevent displacement in the opposite direction. As indicated in FIG. 5, the pawl 11 and the groove 9 are of such a width that their cooperation prevents the piston rod member 8 from rotating relative to the casing 1.

The piston rod member 8 further comprises a thread 12 shaped along its external periphery, and a nut member 13 is screwed onto the thread 12. On the outside the nut member 13 comprises radially protruding projections 14 and 15 extending axially along the outer side of the nut member 13 and received in corresponding respective grooves 16 and 17 (FIG. 4) in a surrounding sleeve-shaped adjustment means or second housing element 18. At the end adjacent the casing 1 this adjustment means 18 comprises a circumferential groove 19 receiving a circumferential projection 20 on the casing 1. As a result the adjustment means 18 is rotatable with respect to the casing 1, yet it is prevented from moving axially.

The nut member 13 is integrally shaped with a tubular indicator 21 extending coaxially with the piston rod member 8 away from the casing 1 between the piston rod member 8 and the adjustment means 18. At the free end projecting outside the adjustment means 18, the indicator 21 comprises an end button or pressure receiving element 22 of substantially the same outer diameter as the adjustment means 18. As indicated in FIGS. 2 and 3, the nut member comprises a circumferential abutment surface 23 at the transition to the tubular indicator. Correspondingly, the adjustment means 18 comprises an inner circumferential abutment surface 24, the abutment surface 23 on the nut member abutting the abutment surface 24 to provide a predetermined stop position as the nut member is displaced in the axial direction relative to the adjustment means 18. The grooves 16 and 17 shaped on the inner side of the adjustment means 18 are of such an extent that the nut member 13 can move freely in the axial direction relative to the adjustment means between the adjacent end of the casing 1 and the inner abutment surface 24 on the adjustment means 18.

The dosage unit also includes a removable cap 25 protecting the needle 5 when the dosage unit is not used. This cap is of such an axial extent that when mounted, its free rim 26 is situated adjacent the adjustment means 18. Axial recesses or grooves are provided close to the free rim 26 of the cap 25, said recesses being situated symmetrically with the same mutual angular separation from one another along the inner side of the cap. These recesses are indicated by the reference numerals 27 and 28 in FIGS. 2 and 3 and receive correspondingly shaped protruding projections 29 and 30, respectively, on the outer side of the casing 1. In this manner the cap can always be situated in a predetermined rotational position relative to the periphery of the casing 1. Preferably the projections 29 and 30 on the casing 1 are shaped to snap into the recesses 27 and 28 on the cap 25.

As shown in FIG. 5, the casing 1 is provided with axially shaped grooves 31, 32, 33, 34 and 35 along its circumference. These grooves are situated with the same mutual angular spacing as the grooves or recesses 27 and 28 on the inner side of the cap 25. These grooves 31–35 on the outer side of the casing 1 cooperate with a projection 36 on the adjustment means 18 which projects inwardly. The grooves 31–35 and the projection 36 are shaped such that the adjustment means 18 can readily be rotated relative to the casing 1 by a user. The projection 36 cooperates with the grooves to releasably hold the casing 1 at any one of five detent positions with respect to the adjustment means, and to provide an audible click as the casing 1 is advanced from one detent position to the next.

A scale is provided on the outer side of the adjustment means 18 at the end adjacent the cap 25 (FIG. 1). This scale comprises a platform 37 with the number 0 thereon. Correspondingly, the cap 25 comprises a knob 38 to be situated opposite the platform 37. The arbitrary positioning of the cap 25 along the circumference of the casing and the corresponding positioning of the adjustment means 18 also relative to the circumference of the casing 1 renders it possible for the user always to be able to situate the knob 38 opposite the platform 37 before the adjustment is initiated.

The dosage unit of FIGS. 1–5 operates in the following manner. Upon positioning of the knob 38 opposite the platform 37 of the adjustment means 18, the desired dosing quantity is set by turning the cap 25 and therefore the casing 1 relative to the adjustment means 18. As a result, the nut member 13 is forced to follow the rotation, the abutment of said nut member 13 against the end of the casing 1 preventing a turning of the adjustment means 18 in the incorrect direction. The rotation of the nut member 13 relative to the piston rod member 8 moves the nut member 13 away from the cartridge by the thread 12, and the indicator moves axially away from the free end of the adjustment means 18. As a result, a coarse measuring scale 39 appears on the outside of the indicator 21. This scale can be configured to

indicate the dosing quantity in question in full turns of the adjustment means 18 relative to the knob 38 on the cap 25, while the scale 40 on the end of the adjustment means adjacent the cap 25 indicates the dosing quantity by portions of a full rotation of the adjustment means 18 relative to the knob 38.

When the desired dosing quantity has been set, the turning of the adjustment means 18 is stopped at a suitable location defined by the inner projection 36 being received in one of the grooves 31–35 on the outside of the casing 1. Subsequently, the user removes the cap 25 and positions the dosage unit at the desired location to insert the needle 5. Then the indicator 21 is forced back into the adjustment means 18 by pressing on the end button 22 until this movement is stopped by the abutment of the nut member 13 against the end of the casing 1 or the abutment of the end button 22 against the adjacent end of the adjustment means 18. The pawl 11 prevents the piston rod member 8 from rotating, and the displacement of the indicator 21 therefore causes displacement of the piston rod member by a corresponding distance, whereby the piston of the cartridge is pressed towards the outlet end of the cartridge. As a result, a quantity of liquid is pressed out of the cartridge, said quantity corresponding to the quantity measured on the measuring scales. After completion of the injection of liquid, the dosage unit is of the same length as before the preadjustment and therefore it maintains an acceptable, uniform appearance.

A suitable choice of material allows the casing 1 to be transparent, whereby the user can always see whether liquid is left in the cartridge. The cap 25 ensures simultaneously that the contents of the cartridge are protected against sunlight. The various parts of the dosage unit are advantageously made of plastics by injection moulding and are relatively easy to manufacture.

FIGS. 6 and 7 illustrate an alternate form of the indicator 21 and the associated nut member 13. On the outside this indicator comprises a protrusion 41 received in a corresponding groove on the inside of the adjustment means 18. At the end opposite the protrusion 41, a circumferential groove 42 is provided for the fastening of a loose end knob (not shown) shaped like the end knob 22.

Many modifications can be made to the first embodiment without thereby deviating from the scope of the invention. The piston rod member may, for instance, be of different cross sections depending on the shape of the ratchet device, and the piston rod member may be prevented from rotating by a suitable shaping of the opening through which the piston rod member passes into the casing 1. Mating teeth may be provided on the end of the nut member 13 adjacent the casing 1 as well as on the abutting end of the casing 1. These teeth are preferably shaped as cooperating barbs preventing a mutual rotation of the casing 1 and the nut member towards a stronger tension. These barbs allow a slight turning in the opposite direction.

As illustrated in FIG. 1, the cap 25 is of a non-circular cross section at the end opposite the adjustment means 18 when said cap is secured on the dosage unit. In this manner it is easy to handle the cap during the mounting procedure. Furthermore, a clip 43 is provided which secures the dosage unit to a pocket in a manner similar to a fountain pen.

The second preferred embodiment of FIGS. 8–19 is similar in many respects to the first preferred embodiment described above. In view of these similarities, corresponding elements in the second embodiment are identified with the same reference numeral as in the first embodiment, with the addition of a prime. Points of similarity between the two embodiments will not be repeated, and the following discussion will focus on the differences between these embodiments.

As best shown in FIGS. 8, 9 and 10, the illustrated disposable syringe includes a removable cap 25' which fits against the second housing element 18'. The second housing element 18' defines a projecting element 44', and the cap 25' defines a mating recess 45'. FIG. 10 shows the way in which the projecting element 44' fits within the recess 45' to define a zero position when the cap 25' is moved against the second housing element 18'. When it is desired to rotate the cap 25' with respect to the second housing element 18', the cap 25' is moved to the position shown in FIG. 9, in which the projecting element 44' is positioned outside of the recess 45', thereby allowing rotation.

The nut element 13' is quite similar to that shown in FIGS. 6 and 7, and the second housing element 18' includes an internal rib 46' that cooperates with the protrusion 41' to define a stop position, beyond which the nut element 13' cannot move. The pressure receiving element 27' defines an array of internal ribs 47' on its internal surfaces, and these ribs 47' are configured to snap into and to engage the circumferential groove 42' in the nut element 13'. These ribs 47' are best shown in FIGS. 11 and 18. In this way assembly of the syringe is facilitated, without requiring adhesives of any type.

FIGS. 11 and 12 show the manner in which the first housing element 1' includes a projection 29' that is shaped to fit into any one of five equally spaced recesses 27' in the cap 25'.

As best shown in FIGS. 14, 15 and 17, the first housing element 1' defines a circumferential lip 48' at its forward end, as well as a circumferential array of lugs 49'. The retaining cap 7' defines a mating groove 50', and a circumferential array of mating recesses 51'. When the retaining cap 7' is snapped in place on the first housing element 1' (FIG. 17), the lip 48' fits within the groove 50' to hold the retaining cap 7' securely in place axially. Similarly, the lugs 49' engage respective ones of the recesses 51' to prevent relative rotation between the retaining cap 7' and the first housing element 1'.

As best shown in FIGS. 14, 15 and 16, the piston rod element 8' defines two diametrically opposed longitudinal grooves 9', and the first housing element 1' includes two diametrically opposed pawls 11', each shaped to fit into a respective one of the grooves 9' to prevent relative rotation between the piston rod element 8' and the first housing element 1'. Ribs 52' (FIGS. 15 and 16) are provided to engage the cartridge 2' frictionally.

As best shown in FIGS. 11 and 14, the first housing element 1' also defines a raised lug 53' which cooperates with five equally spaced grooves in the second housing element 18' (not shown) to define five detented rotational positions of the first housing element 1' with respect to the second housing element 18'. As best shown in FIGS. 14 and 18, the first housing element 1' and the nut element 13' define respective ramps 54', 55'. These ramps are oriented to prevent relative rotation in a selected direction between the first housing element 1' and the nut element 13' when the ramps 54', 55' engage one another so as to prevent excessive stresses on the pawls 11'.

As mentioned above, the operation of the embodiment of FIGS. 8–18 is quite similar to that of the first

preferred embodiment, and will not be described again here.

In the first and second embodiments described above, the piston rod is in each case a two-part assembly made up of a piston rod element and a nut element. However, this is not essential for all syringes using the protective cap of this invention, and the third preferred embodiment shown in FIGS. 19–27 includes a one-piece piston rod.

The disposable syringe illustrated in FIGS. 19–27 comprises a first housing element 101 shaped to receive a liquid filled cartridge (see FIGS. 20, 23). The liquid filled cartridge is preferably of a conventional type and comprises at its front end a rubber membrane, which can be pierced by a needle, and at its rear end an axially displaceable piston. The rear end of the first housing element 101 comprises a relatively short external thread 102 capable of cooperating with an internal thread in a second housing element described below.

A needle assembly, comprising a hub 103, a double pointed needle 104 and internal threads 105, is screwed onto the front end of the first housing element 101. This causes the rear end of the needle 104 to penetrate the rubber membrane of the liquid filled cartridge when the latter is pressed into position against the front end of the first housing element 101.

The first housing element 101 is preferably made of a transparent plastic material, and it comprises five equally spaced longitudinally extending ribs 106 (see FIGS. 20 and 21). The disposable syringe further includes a second housing element 110 surrounding at least the rear end of the first housing element 101 and having an internal thread 111 that cooperates with the external thread 102 on the first housing element 101. The mating threads on the first and second housing elements 101, 110 are configured such that clockwise rotation of the first housing element 101 with respect to the second housing element 110 causes the first housing element 101 to be axially displaced towards the rear end of the second housing element 110. The second housing element 110 includes a rear end wall 112, and the syringe further includes a central, axially displaceable piston rod 113. The front end of the piston rod 113 comprises a collar 114, and the rear end of the piston rod 113 extends through an opening 115 in the end wall 112 and terminates in a pressure receiving element 116. A coil spring 117 surrounds the piston rod 113 and is tensioned between the collar 114 and the interior side of the end wall 112. This coil spring 117 tends to press the front end of the piston rod 113 against the piston of the cartridge located within the first housing element 101, and to maintain the pressure receiving element 116 in contact with the exterior of the end wall 112.

The second housing element 110 also comprises a combined pawl and click mechanism 118. This mechanism 118 extends into the interior of the second housing element 110 and includes a projection 119 having the shape of a saw tooth in contact with the exterior surface of the first housing element 101 and in particular the ribs 106 in such a manner that a counterclockwise rotation of the first housing element 101 relative to the second housing element 110 requires a predetermined force which is greater than the force required to cause clockwise rotation. The mechanism 118 is resiliently connected with the second housing element 110 in such a manner that a click is produced when the projection 119 slides over a rib 106 on the exterior of the first housing element 101.

The second housing element 110 includes at its front end an axially extending recess 120, which cooperates with an axially extending rib provided on a protecting cap described below. The second housing element 110 also defines two axially spaced annular grooves 121, 122 which are positioned on the interior side of the second housing element 110 near the front end. The grooves 121, 122 cooperate with an annular locking ring provided on the protecting cap described below.

As shown in FIGS. 21 and 22, the second housing element 110 is composed of two parts 123, 124 which are interconnected with one another at a plane that extends axially of the second housing element 110.

The disposable syringe further includes a protecting cap 130 which carries at its front end a clip 131. The protecting cap 130 defines at an internal surface five axially extending grooves 132, shaped to receive the ribs 106 provided on the exterior surface of the first housing element 101. The mating ribs 106 and grooves 132 form splines that rotationally engage the protecting cap 130 with the first housing element 101. For this reason, when the protecting cap 130 is positioned over the first housing element 101, rotation of the protecting cap 130 automatically causes a similar rotation of the first housing element 101.

The rear end of the protecting cap 130 includes a section 133 of a reduced diameter sized to fit within the front end of the second housing element 110. At the rear end of the portion of the protecting cap 130 having the full diameter of the protecting cap 130, there are provided a number of axially extending ribs 134, and one of these ribs 135 is shaped as a projection which extends into the section 133 of reduced diameter. The projecting rib 135 is shaped to be inserted into the recess 120 so as to prevent relative rotation between the protecting cap 130 and the second housing element 110.

The reduced diameter section 133 defines an external annular locking ring 136 that is shaped to fit into either one of the grooves 121 or 122 on the interior surface of the second housing element 110 (FIGS. 26 and 27).

When delivered to the patient the syringe of FIGS. 19 through 27 is loaded with a liquid filled cartridge, and the protecting cap 130 is inserted in the second housing element 110 with the projecting rib 135 on the protecting cap 130 inserted into the recess 120 in the second housing element 110. In this position, the annular rib 136 is located in the groove 122 (FIG. 26) and the protecting cap 130 is prevented from rotating relative to the second housing element 110.

Before setting the dose to be injected, the patient must axially displace the protecting cap 130 relative to the first housing element 101, preferably to a position in which the annular rib 36 is located in the groove 121 (FIG. 27). At this point, the patient is free to rotate the protecting cap 130 and the first housing element 101 to set the dose. By using the recess 120 as the zero point, the patient can select a desired dose by rotating the protecting cap 130 over an angle corresponding to a given number of the ribs 134 on the exterior surface of the protecting cap 130. Rotation of the first housing element 101 will cause the piston rod 113 to be axially displaced towards the rear end of the second housing element 110, thus axially displacing the pressure receiving element 116 from the exterior side of the end wall 112. After the desired dosage has been selected, the protecting cap 130 is removed and the syringe is now prepared for an injection (FIG. 25).

The injection is effected by depressing the pressure receiving element 116. Such a depression will cause the piston of the cartridge to be axially moved towards the front end of the syringe, thereby delivering the desired preset dosage of liquid from the tip of the needle 104. After the injection has been completed, the protecting cap 130 is reinserted on the end of the housing 101 with the rib 135 located in the recess 120, and the syringe is again ready for presenting an injection of another preset dosage of liquid.

The piston rod 113 defines stop members 140 which cooperate with the interior surface of the end wall 112 if the piston rod 113 is axially displaced over a distance which is longer than acceptable. In this way, the stop members prevent the selection of a dosage that exceeds a predetermined value.

All three embodiments described above are adapted for use with a liquid filled cartridge. This is convenient for many applications, because the material for the first housing element can be chosen without concern for possible adverse reaction with the solution to be injected. However, for some applications, it may be preferable to eliminate the cartridge and use the first housing element with a suitable piston to contain the solution directly.

We claim:

1. In a disposable syringe for injecting a number of measured doses of a liquid, of the type comprising first and second housing elements coupled together to allow rotation of the first housing element with respect to the second housing element, said first housing element adapted to receive a quantity of liquid and comprising means for mounting a liquid outlet needle at a front end thereof, said second housing element having a rear end situated opposite the front end of the first housing element, the improvement comprising:

a piston rod disposed in the second housing element to move axially therein, said piston rod comprising a rod element and a nut element, said rod element coupled to the first housing element to move axially therein without relative rotation therewith, said nut element threaded to the rod element for telescoping movement therewith and configured to move axially in the second housing element without relative rotation therein; and

a pressure receiving element on the nut element;

said housing, rod, nut and pressure receiving elements cooperating such that relative rotation between the housing elements in a selected direction causes relative rotation between the rod and nut elements and thereby increases the effective length of the piston rod and causes the pressure receiving element to extend from the second housing element such that a measured quantity of liquid is expressed from the needle when the pressure receiving element is moved back toward the second housing element.

2. The invention of claim 1 wherein the first and second housing elements are coupled together for rotation without axial displacement therebetween.

3. The invention of claim 1 wherein the pressure receiving element defines a first stop surface that limits travel of the nut element inwardly, towards the first housing element.

4. The invention of claim 2 wherein the nut element defines an axially oriented scale positioned to indicate the axial position of the nut element with respect to the second housing element.

5. The invention of claim 4 wherein the scale is integrally formed on the nut element.

6. The invention of claim 1 wherein the first housing element is configured to receive a cartridge having a pierceable diaphragm at a front end thereof, a slideable piston at a rear end thereof, and containing the quantity of liquid.

7. The invention of claim 2 wherein the nut element defines at least one radially protruding, axially extending projection on an exterior portion thereof, and wherein the projection is received in an axially extending groove in an inner portion of the second housing element.

8. The invention of claim 1 wherein the nut element comprises a second stop surface configured to contact the second housing element to limit axial movement of the nut element out of the second housing element.

9. The invention of claim 1 wherein the nut element and the pressure receiving element are substantially axially symmetrically shaped, and wherein the pressure receiving element defines an outer diameter substantially equal to that of the second housing element.

10. The invention of claim 1 further comprising

a removable protective cap configured to receive the first housing element and substantially abut the second housing element while mounted on the first housing element; and

means for releasably coupling the protective cap and the first housing element for rotation together such that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

11. The invention of claim 10 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise scale means for measuring relative rotation of the protective cap with respect to the second housing element.

12. The invention of claim 11 further comprising means for providing detents at selected rotational positions of the first housing element with respect to the second housing element.

13. The invention of claim 12 wherein the coupling means allows the protective cap to receive the first housing element in multiple different angular positions of the protective cap with respect to the first housing element to allow the protective cap to be oriented at a selected position with respect to the second housing element, regardless of the detent rotational position of the first housing element in the second housing element.

14. The invention of claim 10 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise interlocking means for defining a selected angular position of the protective cap with respect to the second housing element.

15. The invention of claim 14 wherein the interlocking means comprises a recess on the rear portion of the protective cap and a projection on the front portion of the second housing element, said projection shaped to fit into the recess to define the selected angular position.

16. The invention of claim 1 wherein the rod element defines at least one toothed axial groove, and wherein the rod element is coupled to the first housing element by at least one pawl that rides in the groove to prevent rotation of the rod element in the first housing element.

said pawl engaging the toothed groove to prevent retraction of the rod element.

17. The invention of claim 16 wherein the at least one groove in the rod element comprises two diametrically opposed grooves, and wherein the at least one pawl comprises two pawls, one riding in each of the grooves.

18. The invention of claim 16 wherein the liquid is contained in a cartridge and wherein the first housing element comprises a locking ring that snaps in place to lock the cartridge within the first housing element.

19. The invention of claim 18 wherein the locking ring mechanically interlocks with a mating portion of the first housing element to prevent rotation therebetween.

20. In a disposable syringe for injecting a number of measured doses of a liquid, of the type comprising first and second housing elements coupled together to allow rotation of the first housing element with respect to the second housing element, said first housing element adapted to receive a quantity of liquid and comprising means for mounting a liquid outlet needle at a front end thereof, said second housing element having a rear end situated opposite the front end of the first housing element, the improvement comprising:

a piston rod disposed in the second housing element to move axially therein, said piston rod comprising a piston actuating end and a force receiving end, said force receiving end positioned at the rear end of the second housing element when in an initial position;

means, responsive to relative rotation between the first and second housing elements, for causing the force receiving end of the piston rod to move away from the initial position to preset a dose to be delivered through the needle when the force receiving end is returned to the initial position;

a protective cap removably mounted over the front end of the first housing element to protect the needle; and

means for releasably coupling the protective cap and the first housing element for rotation together such that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

21. The invention of claim 20 wherein the protective cap is configured to receive the first housing element such that a front portion of the second housing element substantially abuts a rear portion of the protective cap when the protective cap is mounted in place over the first housing element.

22. The invention of claim 21 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise scale means for measuring relative rotation of the protective cap with respect to the second housing element.

23. The invention of claim 22 wherein the scale means comprises a circumferential scale on the rear portion of the protective cap and a marker on the front portion of the second housing element.

24. The invention of claim 20 wherein the releasably coupling means comprises a set of interengaging splines on the protective cap and the first housing element.

25. The invention of claim 24 wherein the splines are configured to allow the protective cap to receive the first housing element in multiple different angular positions of the protective cap with respect to the first housing element.

26. The invention of claim 21 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise interlocking means for defining a selected angular position of the protective cap with respect to the second housing element.

27. The invention of claim 26 wherein the interlocking means comprises a recess on the rear portion of the protective cap and a projection on the front portion of the second housing element, said projection shaped to fit into the recess to define the selected angular position.

28. The invention of claim 20 wherein the piston rod comprises a rod element and a nut element threadedly engaged with the rod element, and wherein the nut element is configured to move axially without rotating in the second housing element.

29. The invention of claim 28 further comprising ratchet means for preventing the rod element from retracting from the first housing element while allowing the rod element to move into the first housing element.

30. The invention of claim 20 wherein the first housing element is configured to receive a cartridge having a pierceable diaphragm at a front end thereof, a slideable piston at a rear end thereof, and containing the quantity of liquid.

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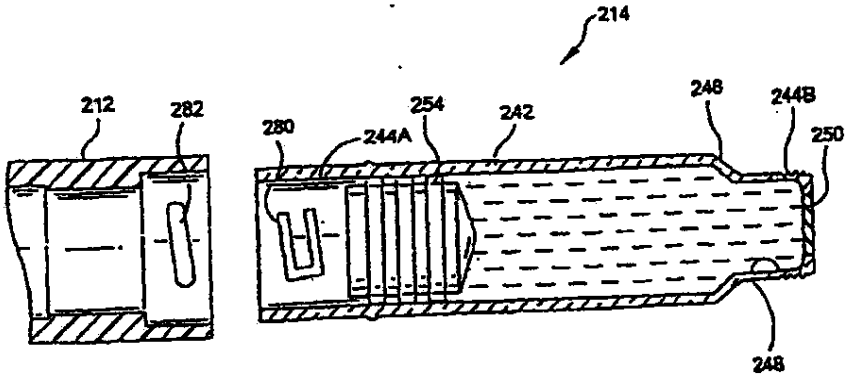

(57) Abstract

This invention relates to a drug cartridge assembly for use with a reusable body assembly of a medication delivery pen. The drug cartridge is disposable and is in the form of a single integral unit having a generally tubular barrel with a distal end defined by an inwardly converging shoulder and an open proximal end. A smaller diameter neck projects distally from the shoulder of the barrel, and is provided with a pierceable and resealable elastomeric seal or septum securely mounted across the open distal end defined by the neck. Medication is pre-filled into the integral cartridge assembly and is retained therein by an elastomeric stopper or plunger. The plunger is in sliding fluid-tight engagement with a tubular wall of the barrel. Distally directed forces on the plunger urge the medication from the cartridge. The proximal end of the tubular barrel is configured for interconnecting the drug cartridge with a pen body assembly and the distal end of the tubular barrel is configured to securely but releasably engage a needle cannula assembly.

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UNITED STATES PATENT APPLICATION

DISPOSABLE, PRE-FILLED DRUG CARTRIDGE

FIELD OF THE INVENTION

The present invention generally relates to drug delivery devices, and more specifically relates to disposable, pre-fillable drug cartridge for use with a reusable body portion of an injection device for injecting drugs or medicaments into patients which are commonly known in the field as pens.

BACKGROUND OF THE INVENTION

Hypodermic syringes are used to deliver selected doses of medication to patients. The prior hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the syringe barrel includes a passage communicating with the chamber. A needle cannula may be mounted to the distal end of the syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

Medication to be injected with the prior hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula may be

withdrawn from the vial, and the medication may be injected into a patient by moving the plunger in a distal direction.

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of a week or day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Usually, each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard hypodermic syringe and vial can be inconvenient and embarrassing in these public environments. Examples of syringes are described in U.S. Patent Nos. 5,250,037 (Bitdinger) and 5,667,495 (Bitdinger), and an example of a filler for mixing insulins is described in U.S. Patent No. 5,542,760 (Chanoch), the disclosures of which are hereby incorporated by reference in their entirety.

Medication delivery pens have been developed to facilitate the self-administration of medication. An example of one such medication delivery pen is described in U.S. Patent No. 5,279,585 (Balkwill), which includes a vial holder into which a vial of insulin or other medication may be received, the disclosure of which is hereby incorporated by reference in its entirety. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the vial holder

includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This medication delivery pen is used by inserting the vial of medication into the vial holder. A pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose. Other examples of pens are described in U.S. Patent Nos. 5,645,534 (Chanoch), 5,582,598 (Chanoch) and 5,569,214 (Chanoch), the disclosure of which are hereby incorporated by reference in their entirety.

The user of the pen mounts a double-ended needle cannula to the distal end of the vial holder such that the proximal point cannula of the needle cannula pierces the elastomeric seal on the vial as described, for example, in U.S. Patent No. 5,549,575 (Giambattista et. al.), the disclosure of which is hereby incorporated by reference in its entirety. The user then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The user then removes and discards the needle cannula, and keeps the medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The user then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used again as explained above.

The above described reusable medication delivery pen is effective and much more convenient for self-administration of medication than the typical hypodermic

syringe and separate medication vial. However, it has been found that there is a need for additional features and improvements for such a medication delivery pen. For example, with the increased use of pens for self-injection of drugs other than insulin, there is a need to prevent cross-use of insulin pens with other drugs and/or cross-use of drug cartridges with other pens. The problems associated with cross-use could also pose a potential hazard, where the dose dials of the pens are different, which might result in the administration of the wrong dosage of the drug. This is particularly hazardous where an overdose of insulin could lead to hypoglycemia and ER treatment.

Thus, there has been a need for a pen, as well as a drug cartridge assembly, which would eliminate the problems and limitations associated with the prior devices discussed above, most significant of the problems being cross-use of the pen with other drug cartridge assemblies and/or cross-use of the drug cartridge assembly with other pens.

SUMMARY OF THE INVENTION

In contrast to the prior devices discussed above, it has been found that a pen particularly suited for use in reducing or otherwise eliminating cross-use can be constructed in accordance with the present invention. Specifically, the pen and the drug cartridge assembly of the present invention are keyed, i.e., they have a connection interface which mechanically prevents the cross-use of cartridge assemblies among designated pens by, for example, using matching threads, bayonets or snap fits on the pen and the holding sleeve of the drug cartridge assembly. Also, the cartridge assembly can have an embedded drug cartridge, not readily separable from each other.

Another object of the present invention is to improve the design of the drug cartridge and holder sleeve so that they are a single integral unit for containing the drug, with a rubber septum for multiple needle penetrations along with a standard thread to attach the pen needle. On the far end of the pen needle thread, a connection interface prevents connection to pens other than the one for which use of the drug container is designed. In this way, the drug cartridge assembly will have minimal dead space and an insert molded rubber septum.

BRIEF DESCRIPTION OF THE DRAWINGS

The various features, objects, benefits, and advantages of the present invention will become more apparent upon reading the following detailed description of the preferred embodiment(s) along with the appended claims in conjunction with the drawings, wherein like reference numerals identify corresponding components, and:

Fig. 1 is a top view of the injection pen of the present invention, with Fig. 1A being a end view;

Fig. 2 is a cross-sectional view of the injection pen shown in Fig. 1 with the lead screw retracted;

Fig. 3 is a partial, cross-sectional view of the injection pen similar to Fig. 2 with the lead screw retracted and a drug vial retained therein;

Fig. 4 is an exploded, side view of the cartridge assembly of the present invention and the drug cartridge and the corresponding portion of the pen shown in Fig. 3;

Fig. 5 is a partial, cross-sectional view of the cartridge assembly shown in Fig. 4 assembled;

Fig. 6 is a partial, cross-sectional view of an alternative embodiment of the cartridge assembly of the present invention;

Fig. 7 is a partial, cross-sectional view of another alternative embodiment of the cartridge assembly of the present invention;

Fig. 8 is a partial, cross-sectional view of yet another alternative embodiment of the cartridge assembly of the present invention; and

Fig. 9 is a partial, cross-sectional view of yet another alternative embodiment of the cartridge assembly of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

The medication delivery pen of the present invention is illustrated in Figs. 1 through 5, with the pen being generally designated 10. As shown in Figs. 1-3, the pen includes a pen body assembly 12, a cartridge assembly 14 and a cap 16, with the cartridge assembly being situated between the body assembly and the cap 16 and typically having sufficient medication for several doses. The pen body assembly and the cartridge assembly are keyed, i.e., they have a connection interface which

mechanically prevents the cross-use of cartridges among designated pens by, for example, threadedly engaged by corresponding threads and grooves, bayonet threads and grooves, snap fits or a pair of lugs that mate in a reverse Luer-lock manner. In addition, all of these elements have a generally cylindrical configuration and are arranged coaxially from opposed proximal and distal ends 18 and 20 of the pen 10 respectively to define a generally cylindrical housing which can easily be handled by a patient or medical attendant.

Referring to Figs. 1 and 2, and in greater detail in Fig. 3, the body assembly 12 is used to set a desired dose of medication to be delivered by the pen 10 and includes an advancing member preferably in the form of a lead screw 22 with a distal end 24 movable in the distal direction based on the dose set by a dose setting mechanism within the pen body 12. The dose setting mechanism determines the distance through which lead screw 22 is to be moved during the injection of medication by the pen 10. It is understood, however, that variations from this preferred embodiment may be provided, and are considered to be within the scope of the subject invention. Particularly, the specific construction of the pen body 12, including the mechanisms for advancing the lead screw, may include those, for example, disclosed in U.S. Patent Nos. 5,279,585 (Balkwill), 5,279,586 (Balkwill), 5,549,575 (Giambattista et. al.), 5,569,214 (Chanoch), 5,582,598 (Chanoch) and 5,645,534 (Chanoch), and co-pending U.S. Patent Application Serial No. 08/314,179 (Chanoch et. al.), the disclosures of which are hereby incorporated by reference in their entirety. Accordingly, the particular pen body is not essential to the present invention and is merely a matter of choice.

As shown in Figs. 1-3, and in greater detail in Figures 4 and 5, the cartridge assembly 14 is divided into two parts, i.e., an upper vial retainer 30 and a lower vial

retainer 32, with the lower vial retainer defining a vial retaining cavity 34 formed in the lower vial retainer. As explained further herein, one end 36A of the upper vial retainer 30 is preferably dimensioned and configured to threadedly engage one end 38A of the lower vial retainer 32 and the other end 36B of the lower vial retainer is configured to securely but releasably engage a needle cannula assembly (not shown). The particular needle cannula assembly is not essential to the present invention and may include the type disclosed in co-pending U.S. Patent Application (P-4059) filed on September 12, 1997 and entitled "PEN NEEDLE ASSEMBLY," the disclosure of which is hereby incorporated by reference in its entirety. The upper and lower retainers 30, 32 both are described in greater detail below.

The cartridge assembly 14, as shown in Figs. 3, 4 and 5, includes a drug vial or cartridge 40, with the cavity 34 dimensioned and configured to securely receive and retain the drug cartridge therein. The drug cartridge 40 includes a generally tubular barrel 42 with a distal end 44A defined by an inwardly converging shoulder 46 and an open proximal end 44B. A smaller diameter neck 48 projects distally from the shoulder 46 of the barrel 42, and is provided with a large diameter annular bead (not shown) extending circumferentially thereabout at the extreme distal end of the neck. A pierceable and resealable elastomeric seal or septum 50 is securely mounted across the open distal end defined by the neck 48. The seal 50 is held in place by a metallic sleeve 52 which is crimped around the circumferential bead at the distal end of the neck 48. Medication is pre-filled into the drug cartridge 40 and is retained therein by an elastomeric stopper or plunger 54. The plunger 54 is in sliding fluid-tight engagement with the tubular wall of the barrel 42. Distally directed forces on the plunger 54 urge the medication from the pen as explained further below.